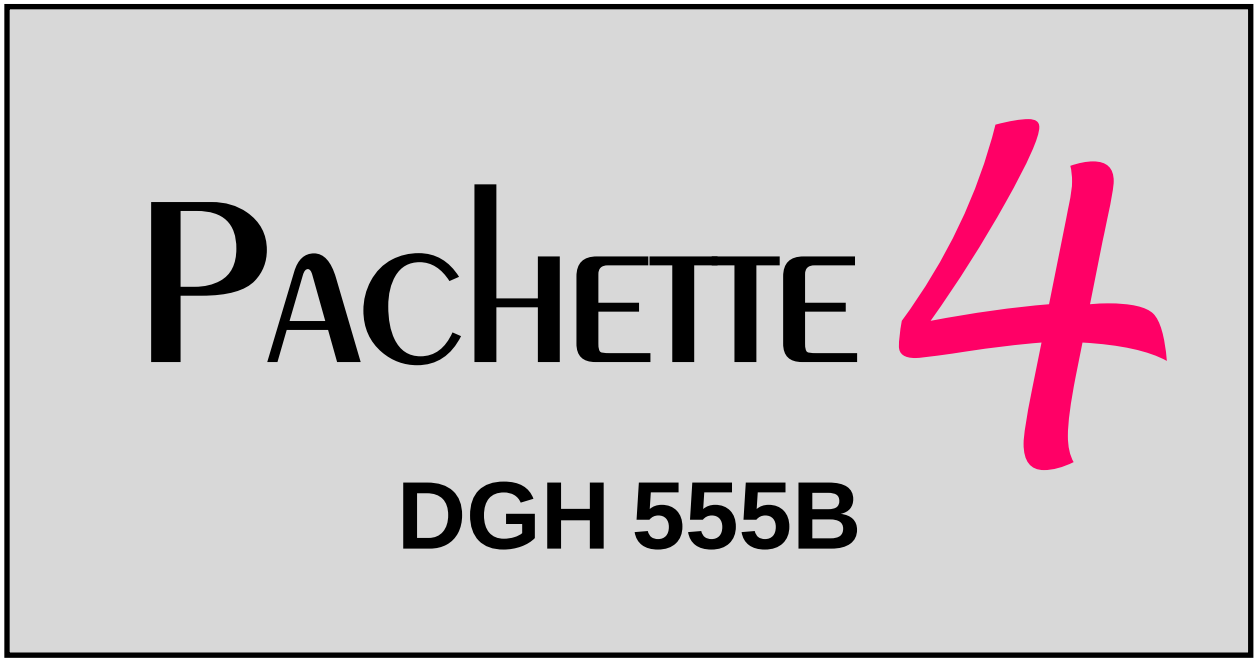
DGH 555B (PACHETTE 4)
ULTRASONIC PACHYMETER



OPERATOR'S MANUAL

For Use with Firmware v3.0.0
And DGH Connect Software v1.1.0

Equipment Manufactured By

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1. Introduction, Classification and Indications For Use

1.1 General Device Description

The DGH 555B Ultrasonic Pachymeter (**Pachette 4**) is a portable, battery operated, ultrasonic device that is used in the ophthalmic field for measuring the thickness of the human cornea. Cornea thickness measurements are used in the preoperative evaluation of laser vision correction procedures, and for the evaluation of glaucoma. The DGH 555B is also used as a diagnostic tool in a variety of clinical situations including the general assessment of corneal health related to pathologies and in evaluating corneal swelling following surgery or injury.

The general principle of operation of the DGH 555B Ultrasonic Pachymeter (**Pachette 4**) is as follows: The tip of the ultrasonic transducer (probe) is placed in contact with the patient's cornea which automatically initiates a measurement cycle. At the start of the measurement cycle, the electronic circuit board transmits voltage pulses to the ultrasonic transducer (probe). The piezoelectric element in the transducer converts these voltage pulses into ultrasonic energy, sending a pulse of a high frequency sound waves (20MHz damped to 13MHz) through the eye, and reflected pulses (echos) are received back to the transducer and are converted to voltage pulses. The first echo to be received comes from the anterior corneal surface. If an echo spike from the anterior corneal surface is received within an anticipated time window, the DGH 555B then prepares to receive an echo spike from the posterior corneal surface. Only anterior and posterior echo spikes that fall within specified voltage limits that ensure that the probe tip is perpendicular to the cornea surface are accepted for processing. The time interval between the accepted anterior and posterior echo spikes represents the thickness of the cornea. The time interval is converted to a corresponding distance, or thickness, based on the acoustic velocity through the cornea, and is displayed on the 16 x 2 LCD in units of microns.

1.2 Device Classification

Device: System, Imaging, Pulsed Echo, Ultrasonic
Panel: Radiology
Product Code: IYO
Device Class: II
Regulation Number: 21 CFR 892.1560

Device: Diagnostic Ultrasonic Transducer
Panel: Radiology
Product Code: ITX
Device Class: II
Regulation Number: 21 CFR 892.1570

1.3 Indications For Use

The DGH 555B Ultrasonic Pachymeter (**Pachette 4**) is a portable, battery operated, ultrasonic device that is used in the ophthalmic field for measuring the thickness of the human cornea.

2. Description of Symbols

This symbol indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the equipment, operator or patient.

This symbol indicates the type BF classification and is located on the front and back of the unit.

This mark indicates that Notified Body 0120 (SGS United Kingdom Ltd) has certified the management system of DGH Technology, Inc. meets the requirements of Directive 93/42/EEC Annex II (excluding section 4) for ultrasonic pachymeters.

This symbol located on the DGH 555B indicates that the equipment consists of electronic assemblies and other components that may be subject to Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC of the European parliament, which advises that electrical and electronic devices must not be disposed of as normal domestic refuse. In order to prevent environmental risks or endangerments by non-professional disposal, the disposal of this product, including any accessories, must comply with valid practices as outlined in Directives 2002/96/EC, 2003/108/EC, and 2002/95/EC and local regulations. All electronic components and systems should be returned to Original Manufacturer for disposal.

This symbol instructs the operator to read the operating manual.

This symbol indicates that DGH Technology, Inc. is the manufacturer of the DGH 555B **Pachette 4** device. The YYYY under the symbol indicates the year the device was manufactured.

This symbol indicates that Emergo Europe is the European Authorized Representative for this device.

REF This symbol indicates that the model number of this device is DGH 555B.

SN This symbol indicates the serial number of the device. YYYY indicates the year of manufacture and XXXX indicates the unit number.

3. General Cautions and Warnings, Prescription Device Statement and Operator Qualifications

3.1 General Cautions and Warnings

WARNING: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, gases or in oxygen-rich atmosphere.

WARNING: ELECTRICAL SHOCK HAZARD. Do not open the unit. Refer servicing to qualified service personnel.

3.2 Prescription Device Statement

WARNING: The DGH 555B (**Pachette 4**) is a prescription device and is only to be used by, or under the supervision of, a licensed physician.

3.3 Operator Qualifications

This DGH 555B is intended to be used by trained medical professionals. The medical professional operating the DGH 555B must have a general knowledge of the use of ultrasonic medical devices. Use of the DGH 555B requires adequate dexterity to position the probe safely. The DGH 555B uses audio feedback to inform the operator of the scan status.

4. Use Of Ultrasound In Ophthalmic Measurement

4.1 Introduction To Ultrasound

Ultrasound offers a non-invasive method to examine the interior of solid objects. Ultrasonic pulses consist of sound waves of a frequency level too high to be heard by the human ear. When a sound impulse strikes an interface, some sound is reflected, and some sound is transmitted. Because some sound will pass through the surface and be reflected by the next surface, complex structures can be examined with ultrasound. When ultrasound penetrates an object with several interfaces, the reflected ultrasound can be observed as a waveform with peaks that are related to the positions of the interfaces.

The DGH 555B transducer emits ultrasound pulses and detects ultrasound signals that have been reflected back. The time delay between the echoes is used to calculate distances between surfaces in the eye.

NOTE: Ultrasound cannot travel through air because air is not dense enough for the high frequency waves to propagate. Ultrasonic measurements must therefore be performed by direct contact or through a denser medium such as water.

4.2 Using Ultrasound To Ascertain Correct Probe Alignment

Sound travels in straight lines, so the direction of reflected sound is based solely on its angle of incidence. Sound hitting an interface perpendicularly will reflect back along the same path that it approached (Figure 4.2.1). Sound hitting an interface at an angle will reflect at an angle away from the source (Figure 4.2.2). The transmitted sound will continue on at a lesser amplitude because of reflected energy lost at the interface.

When reflected ultrasound is shown as a two-dimensional waveform, the peaks are related to the positions of the interfaces. By comparing the relative height (intensity) of the peaks, one can determine the angle at which the sound is striking it. Steadily diminishing peaks are an indicator that the ultrasound is not perpendicular to the interfaces

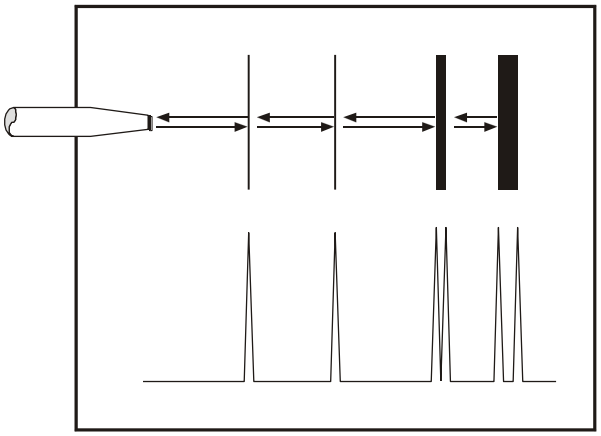


Fig 4.2.1: Sound hitting an interface perpendicularly.

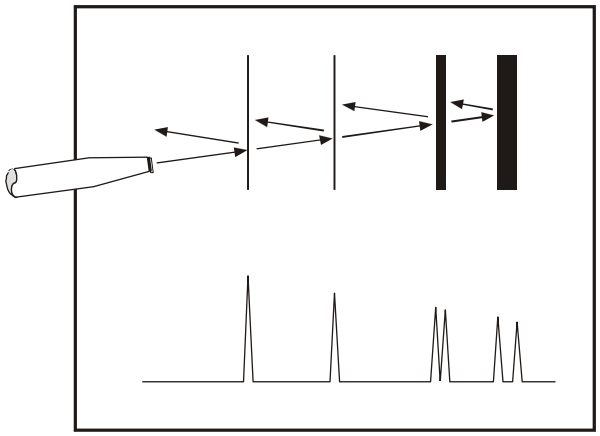


Fig 4.2.2: Sound hitting an interface at an angle

Using these properties of ultrasound, the alignment of an ultrasound beam through the eye can be determined. Proper alignment is crucial to the accuracy of measurements.

4.3 Ultrasonic Measurement

The speed of sound increases in denser materials. Liquids or substances containing large amounts of water conduct ultrasound very well; air does not conduct ultrasound. Using the relationship between the density of a material and the speed of sound, ophthalmic pachymeters obtain distances in the eye by performing a two-step process.

First, a pulse of sound is timed as it travels through the cornea, reflects off the back of the cornea, and returns to the transducer.

Second, the thickness is calculated based on the travel time and the speed of sound through the eye:

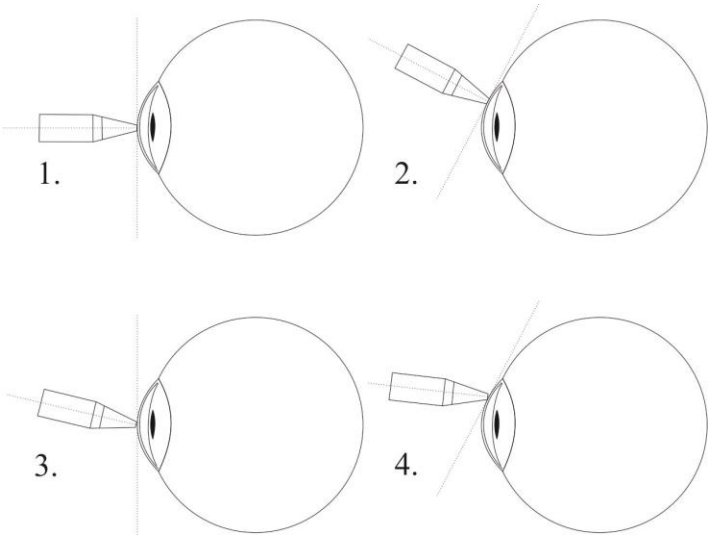
$$\text{distance} = \frac{\text{velocity} \times \text{time}}{2}$$

All thickness measurements are based on a corneal velocity of 1640 m/sec.

4.4 Proper Applanation for Taking A Measurement

Proper applanation is necessary for obtaining an accurate measurement. Proper applanation occurs when the flat tip of the probe comes into full contact with the cornea perpendicular to the cornea surface. The user must ensure that pressure against the cornea is minimized.

The diagram below illustrates correct and incorrect alignment of the probe tip to the cornea.



1 and 2: CORRECT: The probe IS perpendicular to the corneal surface.
3 and 4: INCORRECT: The probe IS NOT perpendicular to the corneal surface.

Fig 4.4.1 Correct and Incorrect Applanation

While in *Measurement Mode*, the **Pachette 4** will automatically take a measurement whenever the tip of the probe is properly applanated to the cornea.

⚠ **WARNING:** Moving or realigning the probe tip while it is in contact with the cornea or applying pressure while measuring the cornea may cause damage to the cornea. When changing position or alignment of the probe, it is necessary to disengage contact, reorient and then gently re-applanate.

5. Ultrasonic Exposure And Intensities

5.1 Tissue Exposure To Ultrasound Energy

The ultrasound energy emitted by the **Pachette 4** is low intensity and will have no adverse effects on the patient and/or operator. However, the operator is still cautioned to perform examinations using the principle of ALARA (As Low As Reasonably Achievable). All examinations should be done so that the patient receives as little ultrasound radiation as possible. Do not hold the probe against the eye or other tissue with the system activated except when making a measurement. Do not make unnecessary measurements.

5.2 Ultrasonic Intensities

The **Pachette 4** has only one mode, and ultrasonic intensity settings are not under the control of the operator. Thus, the values below are the values to be expected for a typical transducer.

Since the DGH 555B **Pachette 4** is not capable of exceeding either a TI of 1.0 or an MI of 1.0 in any operating mode, the output of the system is reported as shown in the Table below.

The appropriate Thermal Index is the Thermal Index for Soft Tissue, TIS, for the non-scanning case with a beam aperture of less than 1.0 cm.

Output Summary Table

Transducer Model (used with DGH 555B)	**$I_{spta.3}$**	**TI Type**	**TI Value**	**MI**	**$I_{pa.3}$ @ MI_{max}**
DGH2006	1.0 mW/cm^2	TIS non-scan, $A_{aprt} < 1.0$	0.0005	0.052	2.4 W/cm^2

The acoustic output values given above are based on a presumed attenuation of ultrasound on tissue, as developed by the U.S. Food and Drug Administration in 1985, and later incorporated into other international Standards.

The attenuated intensity in the eye at the transducer focus (corresponding to maximum intensity) may be calculated according to the formula recommended by the FDA:

$$I_t = I_w \times e^{(-0.069 \times f \times z)}$$

where I_t is the estimated in situ intensity, I_w is the measured intensity in water at the focus of the transducer, f is the ultrasonic frequency, and z is the distance from the face of the probe to the transducer focus, which is the point of measurement (3 millimeter).

The nominal piezoceramic (crystal) frequency of these transducers is 20 MHz. The actual frequency of a particular transducer may vary from this value. The tissue calculations above were done with the measured frequency of the transducer used for the tests.

5.3 Biometric Measurement Capabilities

The following table shows the measurement range for the DGH 555B Ultrasonic Pachymeter (**Pachette 4**)

Measurement Option:	Standard Unit
Range (µm):	200 – 1100 µm
Accuracy (µm):	±5µm
Display Resolution (µm):	1 µm

Measurement Option:	Flap
Range (µm):	95 – 1100 µm
Accuracy (µm):	±5µm
Display Resolution (µm):	1 µm

6. Physical Description

6.1 Front View

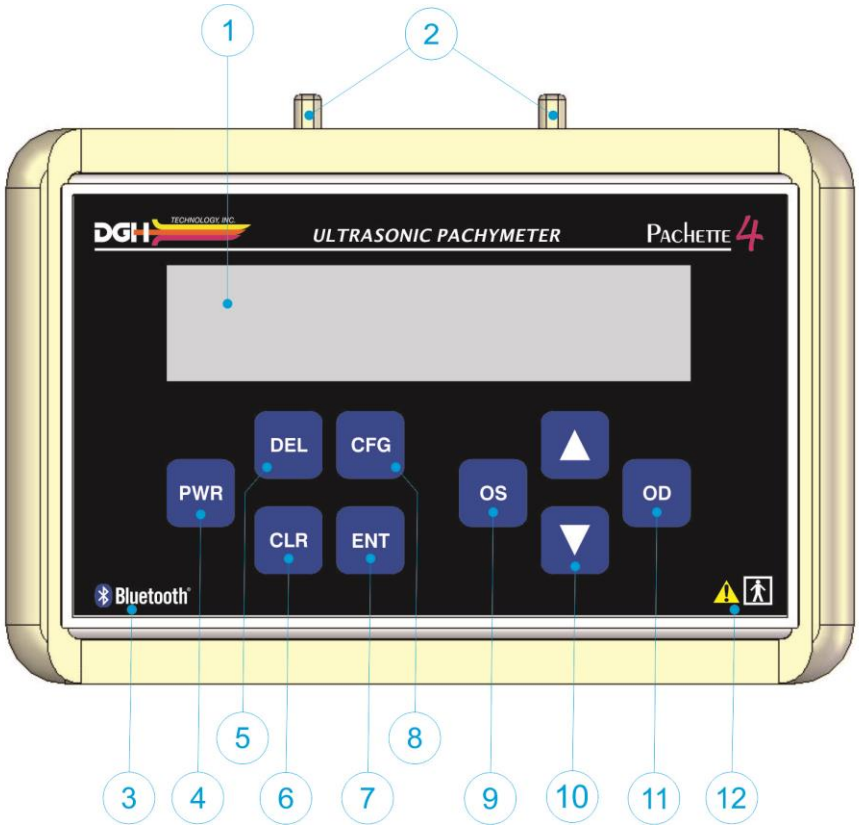


*Fig 6.1.1 The DGH 555B (**Pachette 4**) Front View*

1 LCD Display

16 x 2 character display used to present measurement data and/or configuration parameters to the operator.

2 Probe Clips

Two clips molded into the protective case to place probe between patients.

3 Bluetooth® Wireless Technology Logo

The Bluetooth® Wireless Technology Logo will only appear on the front panel of the unit if the device has the optional Bluetooth® module installed.

4 PWR Key
Pressing this key turns the **Pachette 4** on. When the **Pachette 4** is on, pressing and holding this key turns the **Pachette 4** off. Also used in conjunction with the DEL key to enter the CalBox mode.

5 DEL Key
Used to erase a single measurement from a group of measurements. Also used in conjunction with the PWR key to enter the CalBox mode.

6 CLR Key
This key is used to show the clearing options of the device. The user can clear all measurements, OD measurements, OS measurements, patient information and paired devices. Pressing and holding this key will display the date and time.

7 ENT Key
In measurement mode, pressing key will display battery status. In configuration mode, the key is used to advance to the next configurable parameter. Pressing and holding this key will send measurements to a PC/Printer (only available with Bluetooth® option installed).

8 CFG Key
Used to enter and exit the configuration mode. Also used to display the unit model number, serial number, software version and option number when the key is pressed and held.

9 OS Key
Press key to review or take measurements of the LEFT eye.

10 ▲ / ▼ Keys
Used to review measurements or to program options and numerical values presented on the display.

11 OD Key
Press key to review or take measurements of the RIGHT eye. Also used while in the configuration menu to confirm some device parameters.

12 Device Labels
Refer to Section 2 for descriptions of device classification and attention symbols.

6.2 Back View

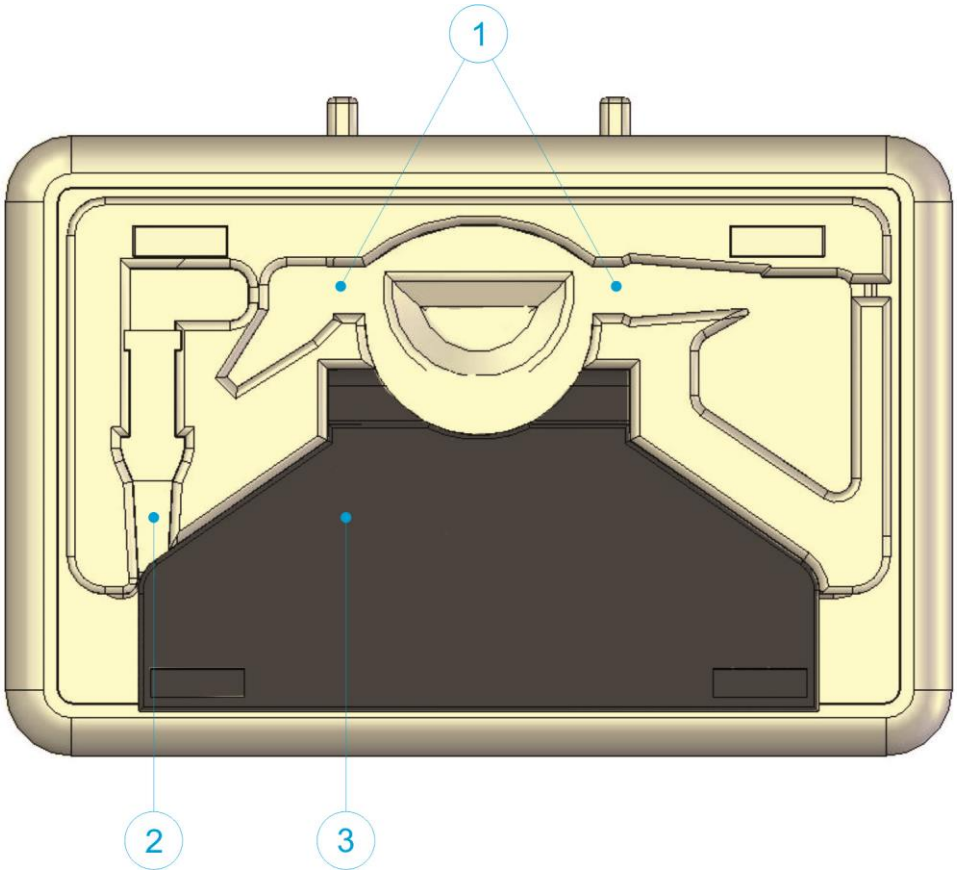


*Fig 6.2.1 The DGH 555B (**Pachette 4**) Back View*

1 Probe Holder
Used to hold or store probe when not in use or during transport.

2 Probe Connector Holder
Used to hold or store probe connector when not in use or during transport.

3 Tilt Stand
Used to place the unit in a tilted position while on a flat surface.

6.3 Side View

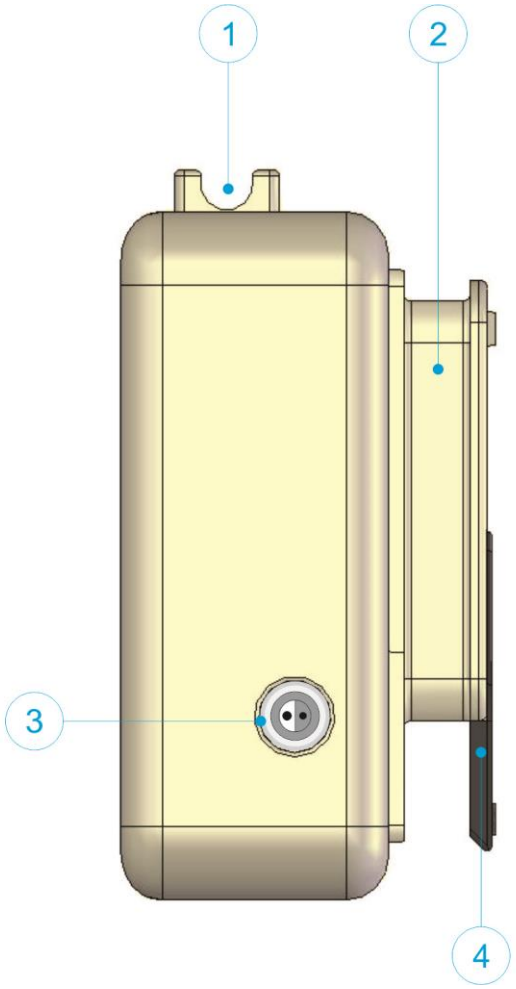


*Fig 6.3.1 The DGH 555B (**Pachette 4**) Side View*

1 Probe Clips
Two clips molded into the protective case to place the probe between patients.

2 Probe Cord Wrap
Place to wrap the probe cord when not in use or during transport.

3 Probe Connector
The connector that mates to the connector on the probe cable.

4 Tilt Stand
Used to place unit in tilted position on a flat surface.

6.4 Back Of Unit (Protective Holster Removed)

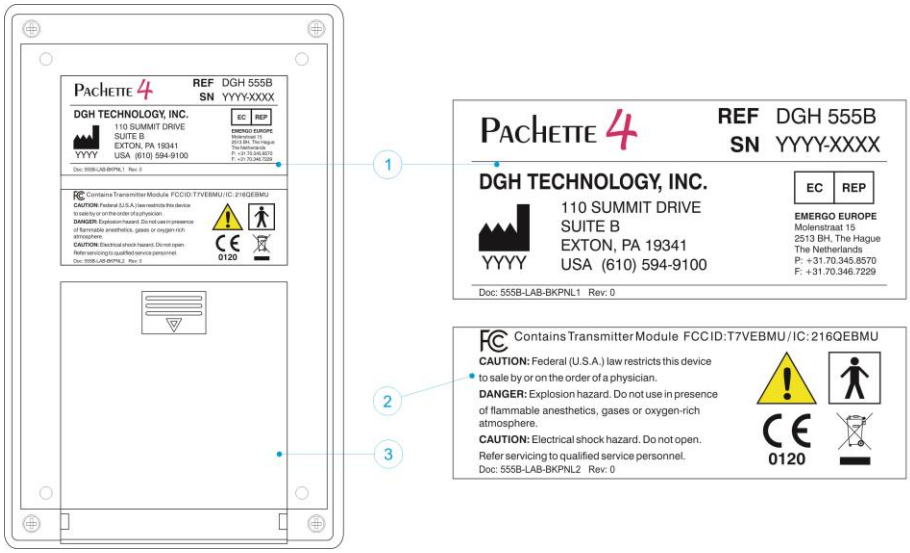

PACHETTE 4
REF DGH 555B
SN YYYY-XXXX
DGH TECHNOLOGY, INC.
110 SUMMIT DRIVE
SUITE B
EXTON, PA 19341
USA (610) 594-9100
YYYY
EC REP
EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands
P: +31.70.345.8570
F: +31.70.346.7229
Doc: 555B-LAB-BKPNL1 Rev: 0
Contains Transmitter Module FCC ID:T7VEBMU / IC: 216QEBMU
CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
DANGER: Explosion hazard. Do not use in presence of flammable anesthetics, gases or oxygen-rich atmosphere.
CAUTION: Electrical shock hazard. Do not open. Refer servicing to qualified service personnel.
Doc: 555B-LAB-BKPNL2 Rev: 0
0120
1
2
3

*Fig 6.4.1 The DGH 555B (**Pachette 4**) Back View with protective holster removed*

1 Unit Identification Label

This label contains the model number and serial number for the unit. It also provides contact information for DGH Technology, Inc.

2 Classification and Attention Label

This label contains classification and attention symbols. Refer to Section 2 for descriptions of device classification and attention symbols.

- **Contains Transmitter Module FCC ID: T7VEBMU / IC: 216QEBMU**

This note only to appear on devices that contain a Bluetooth® wireless module.

3 Battery Door

This door provides access to the battery compartment. See section 16.1 and 16.2 for information on accessing the battery door and changing batteries.

6.5 Probe

*Fig 6.5.1 The DGH 555B (**Pachette 4**) probe*

1 Probe Tip

The portion of the probe energized when taking a measurement

2 Transducer Housing

Contains the transducer and is held by the operator during measurement.

3 Probe Connector

The probe connector plugs into the **Pachette 4** unit. See section 7.1 for instructions on proper connection and disconnection of probe.

6.6 Calibration Verification Box (CalBox)

To check **Pachette 4** calibration, an electronic Calibration Verification Box "CalBox" is used to simulate the thickness of the cornea. Instructions for using the Cal-Box are given in section 4 and they are also printed on the CalBox label.

WARNING: Calibration verification should be performed daily before using the device.

DGH
TECHNOLOGY, INC.
1. With the Pachette 4 turned off, disconnect the probe and then connect the CalBox cable to the Pachette 4.
2. Enter Pachette 4 CalBox Mode by pressing and holding the DEL key while pressing the PWR key.
3. Press the CalBox START key until the LED lights up.
4. Observe that all Pachette 4 measurements are within ±5µm. See user's manual for further details.
5. Exit CalBox mode by pressing the CLR key.
Pachette 4
CalBox
START
Model
DGH 555B

Fig 6.6.1 The DGH 555B (Pachette 4) Electronic CalBox

7. Probe Use and Indicators

The **Pachette 4**'s removable probe contains a piezo-electric element within its transducer housing (See section 6.5). This element creates an ultrasonic pulse (main bang) that is channeled through the clear plastic cone and focused to the point of measurement. The pulse exits the cone and creates a return signal (echo) as it passes through the cornea. The piezo electric element receives the return signal (echo), and the **Pachette 4** analyzes the magnitude of the return signal (echo) in order to calculate corneal thickness.

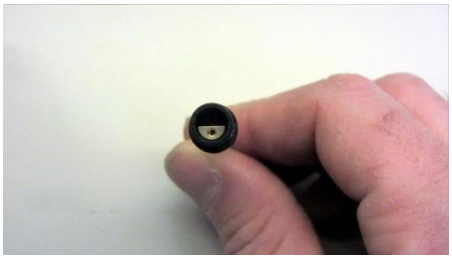
Correct use and maintenance of the probe is essential for collecting accurate measurements. The operator must ensure that the probe is properly cleaned and connected so that the device can perform a probe self-test.

The **Pachette 4** automatically performs a self-test to check the functionality of the probe. This test is done every time the device is put into *Measurement Mode*. Typically the operator will be unaware that a self-test is occurring, however the operator must know how to react if an error message is produced.

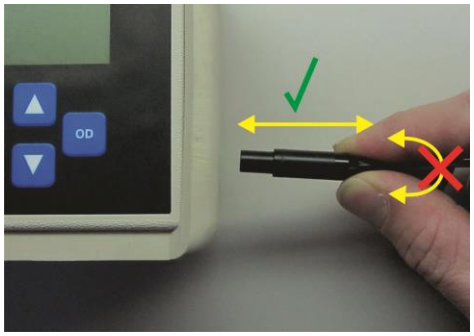
7.1 Inserting and Removing the probe

⚠ **WARNING:** Twisting the probe connector while it is being inserted/removed from the **Pachette 4** can damage both the probe and **Pachette 4**.

7.1.1 Align the probe connector prong to fit into the **Pachette 4**. The prong is a half-circle with a small hole in it.

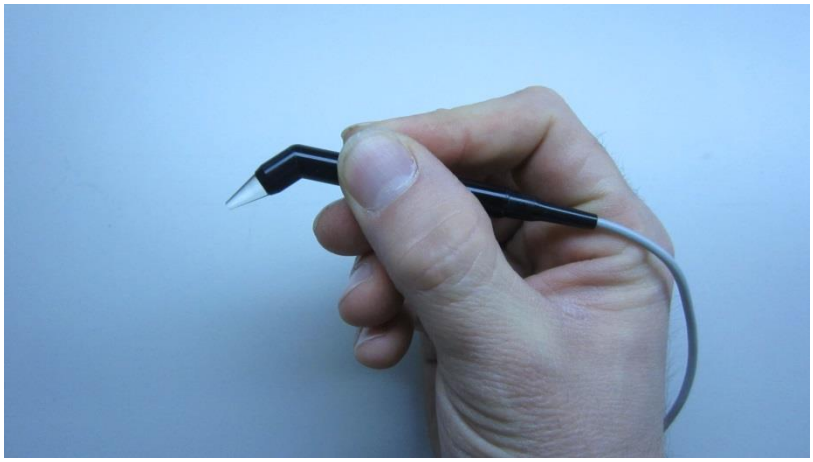


7.1.2 The connectors are designed to go together WITHOUT twisting. When inserting or removing the probe, slide the connectors together without twisting.



7.2 Holding the Probe

While handling the probe, try to avoid contact with the probe tip (clear plastic cone) so as to avoid contamination. Touching the probe tip with ungloved hands may leave a residue that will cause the device to return an error message when self-testing (See section 7.3).

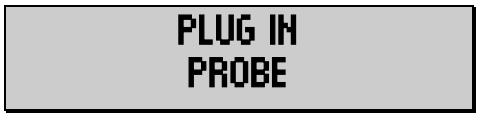


7.3 'Check Probe' Error Message

This message typically indicates an error generated by the probe tip being wet. Dry the tip and cycle the device power off then back on. If drying the tip of the probe does not resolve the error, then the probe may have degraded to the point that it will require replacement.

7.4 'Plug In Probe' Error Message

This message occurs when: (1) the detachable probe is not mated or is improperly mated to the unit, or (2) the probe is defective. If the probe is found to be defective, remove defective probe by holding the probe connector and gently pulling straight out of the unit.



WARNING: Do not twist probe as this could damage connectors. Properly align the probe connector and gently push in until properly seated.

7.5 'PQF Failed' Error Message

This message usually indicates a hardware failure occurred within the unit and the unit must be returned for repair. See section 19.1 for service information.

8. Verifying Pachette 4 Calibration

Pachymeter calibration is verified by using the electronic Calibration Verification Box (CalBox) that is supplied with the **Pachette 4** (see section 6.6). The CalBox *does not* calibrate the pachymeter, it generates a sequence of precise, predetermined pulses that are measured by the pachymeter. The *user* must confirm that each measurement generated by the CalBox falls within the acceptable range (see 8.1.5).

⚠ **WARNING:** Calibration verification should be performed daily before using the device.

8.1 Procedure For Verifying Calibration

8.1.1 With the **Pachette 4** turned off, disconnect the probe by holding the connector and gently pulling straight out of the unit. (Caution: Do not twist probe as this could damage connectors)

8.1.2 Connect the CalBox to the **Pachette 4** by inserting the CalBox lead into the probe connector.

8.1.3 Enter the CalBox mode by pressing and holding the **Pachette 4**'s DEL key and then press the PWR key.

8.1.4 Press and hold the CalBox START key until the green LED on the CalBox lights up, and the **Pachette 4** will begin taking measurements.

- If the LED fails to light, or turns off before the test sequence is complete, or if the 'Poor Applanation' message is displayed, the CalBox 9v alkaline battery needs to be replaced.

- If no measurements are taken within 2 ½ minutes after the CalBox START button has been pressed, the CalBox will automatically turn off.

8.1.5 Refer to the following table that corresponds with your unit.

- If the **Pachette 4** is a Standard Unit, refer to Table 8.1.5a. The device will show calibration measurements of 200µm through 1000µm, in steps of 100µm.

- If the **Pachette 4** is a Flap Option Unit, refer to Table 8.1.5b. The device will show calibration measurements of 100 µm through 1000 µm, in steps of 100 µm.

- All values are based on a corneal velocity of 1640 m/sec and should be within +/- 5µm of the measurement pulse.

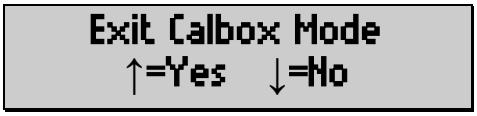
Table 8.1.5a : Standard Pachette 4 Measurement Range Chart	
Measurement 1: 200 µm pulse	Acceptable Result: 195 µm – 205 µm
Measurement 2: 300 µm pulse	Acceptable Result: 295 µm – 305 µm
Measurement 3: 400 µm pulse	Acceptable Result: 395 µm – 405 µm
Measurement 4: 500 µm pulse	Acceptable Result: 495 µm – 505 µm
Measurement 5: 600 µm pulse	Acceptable Result: 595 µm – 605 µm
Measurement 6: 700 µm pulse	Acceptable Result: 695 µm – 705 µm
Measurement 7: 800 µm pulse	Acceptable Result: 795 µm – 805 µm
Measurement 8: 900 µm pulse	Acceptable Result: 895 µm – 905 µm
Measurement 9: 1000 µm pulse	Acceptable Result: 995 µm – 1005 µm

Table 8.1.5b : 'Flap Option' Pachette 4 Measurement Range Chart	
Measurement 1: 100 µm pulse	Acceptable Result: 95 µm – 105 µm
Measurement 2: 200 µm pulse	Acceptable Result: 195 µm – 205 µm
Measurement 3: 300 µm pulse	Acceptable Result: 295 µm – 305 µm
Measurement 4: 400 µm pulse	Acceptable Result: 395 µm – 405 µm
Measurement 5: 500 µm pulse	Acceptable Result: 495 µm – 505 µm
Measurement 6: 600 µm pulse	Acceptable Result: 595 µm – 605 µm
Measurement 7: 700 µm pulse	Acceptable Result: 695 µm – 705 µm
Measurement 8: 800 µm pulse	Acceptable Result: 795 µm – 805 µm
Measurement 9: 900 µm pulse	Acceptable Result: 895 µm – 905 µm
Measurement 10: 1000 µm pulse	Acceptable Result: 995 µm – 1005 µm

⚠ **WARNING:** If ***ANY*** of the calibration measurements are outside of the acceptable result tolerance, contact DGH Technology, Inc.

8.1.6 When all measurements are complete, exit CalBox Mode by pressing the CLR key on the **Pachette 4**.

8.1.7 The **Pachette 4** will require confirmation to exit CalBox mode. Press the ▲ key to select 'Yes'.



8.1.8 Disconnect the CalBox by pulling the lead straight out.

8.1.9 Reconnect the probe. The **Pachette 4** is now ready to take measurements.

⚠ **WARNING:** You must exit CalBox Mode before attempting corneal measurements.

9. Power Modes

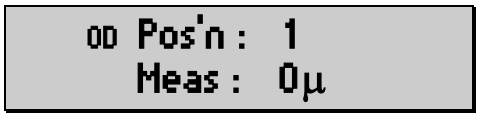
During use, the **Pachette 4** is designed to automatically enter power-saving modes to conserve battery life. The user should be familiar with all modes before using the device.

9.1 Measurement Mode

Measurement Mode is when the device is at full power. In *Measurement Mode* the device is energizing the probe. When the probe is properly applanated (See section 4.4) to the cornea in *Measurement Mode*, the unit will detect contact and automatically take a measurement. *Measurement Mode* can take either *Continuous Averaging* measurements or *Mapping* measurements.

- When *Measurement Mode* is set to *Continuous Averaging,* the device will display:

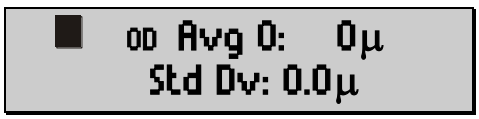
- When *Measurement Mode* is set to *Mapping*, the device will display:



9.2 Standby Mode

This is when the device is not energizing the probe. The unit automatically goes into *Standby Mode* if there has been no attempt at measurement for one minute. The device will not be able to detect corneal contact in Standby Mode.

Standby Mode is indicated by a beep and flashing cursor in the upper left-hand corner of the display. While in *Standby Mode*, the display will stay on and you will be able to view measurements and access the configuration menu. You will not be able to take a measurement in *Standby Mode*.



To exit *Standby Mode* press the PWR key, this will put the unit back into *Measurement Mode.* The 1 minute delay can be adjusted from 0.5 to 9.5 minutes by accessing the configuration menu as described in section 13.4.1.

9.3 Sleep Mode

The device will automatically enter *Sleep Mode* if it has been in *Standby Mode* for three minutes and there have been no key presses. When entering *Sleep Mode* the **Pachette 4** will display a 'Powering Down' message:

After the 'Powering Down' message, the display will go blank and the unit will appear to be off, but all the measurements that were taken can still be retrieved.

To bring the device out of *Sleep Mode*, press the PWR key. The unit will perform an internal test and display battery status.

If there are no currently active measurements, the device will show an empty measurement screen. If there are active measurements, the **Pachette 4** will display:

- Press the ▲ key to clear all measurements.
  Press the ▼ key to retrieve all measurements.

- After exiting *Sleep Mode*, the device will return to *Measurement Mode.*

9.4 Powering Down

The unit is powered down by pressing and holding the PWR key. The device will emit a beep and turn off.

NOTE: If the device is powered down by the user, only measurements in memory will be stored. See sections 10.1 and 10.2 for information on memory.

9.5 Checking Battery Power

Battery power will be displayed every time the device is powered on. Battery power can also be checked at any time by quickly pressing the ENT key.

10. Patient Modes

10.1 Single Patient Mode

NOTE: Single Patient Mode is available on all **Pachette 4** devices; however exporting measurements from the device is only available with Bluetooth® module option installed.

By default, every time the **Pachette 4** is turned on, it is in Single Patient Mode. Single Patient Mode allows the user to start taking measurements immediately. Single Patient Mode is indicated by a blank space on the lower left-hand side of the screen.

Once the user completes taking measurements for both the right and left eye, the measurements must be cleared before a new measurement group can be initiated. The device can only remember a single patient's measurements while operating. Therefore it is necessary to either write down or export the measurements.

NOTE: In Single Patient Mode the device can take either *Continuous Averaging* or *Mapping* measurements. However, if the *Measurement Mode* is changed it will clear the measurements for all patients stored in memory.

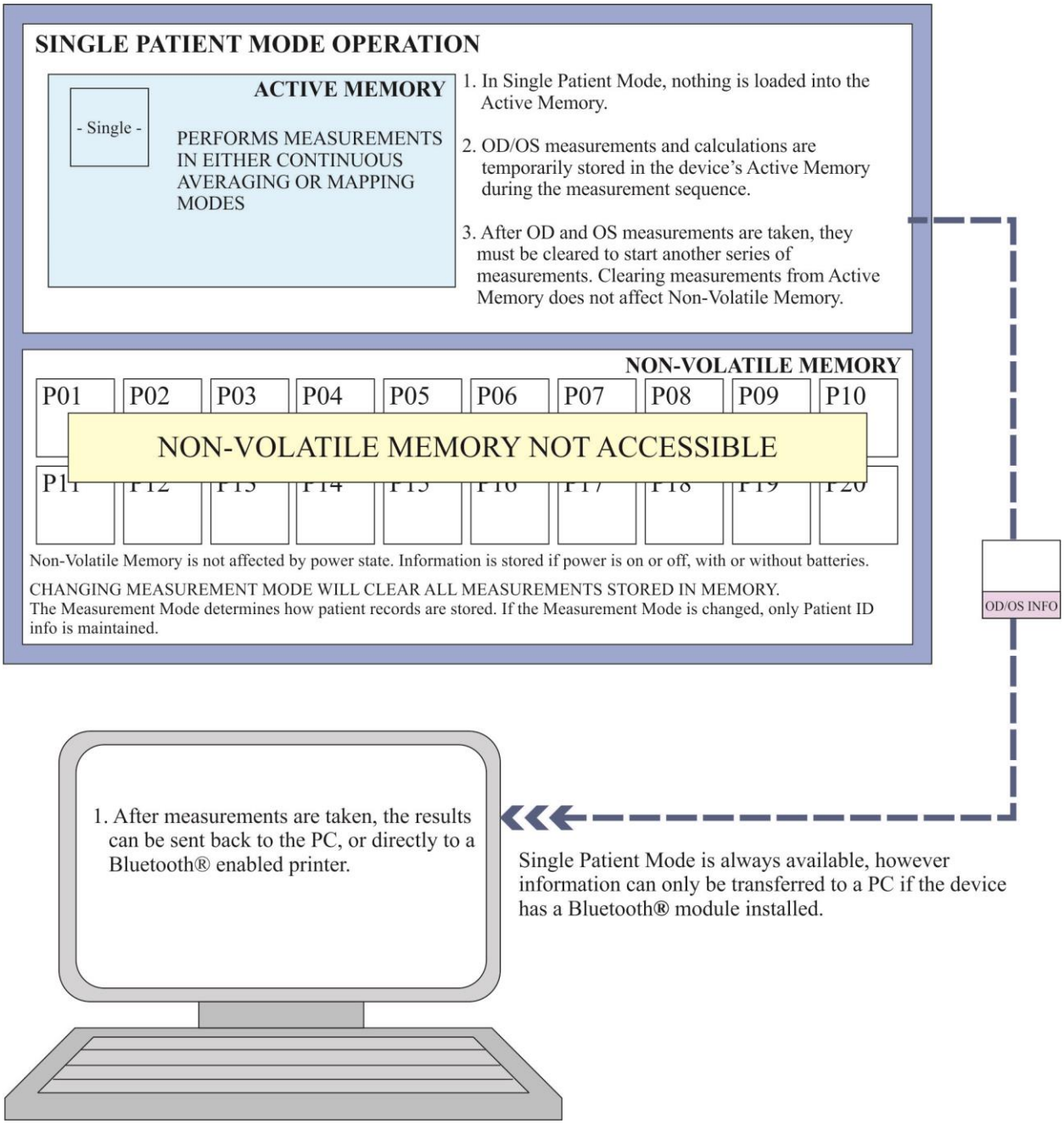
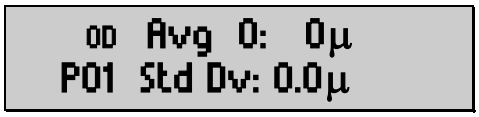

SINGLE PATIENT MODE OPERATION
ACTIVE MEMORY
- Single -
PERFORMS MEASUREMENTS IN EITHER CONTINUOUS AVERAGING OR MAPPING MODES
1. In Single Patient Mode, nothing is loaded into the Active Memory.
2. OD/OS measurements and calculations are temporarily stored in the device's Active Memory during the measurement sequence.
3. After OD and OS measurements are taken, they must be cleared to start another series of measurements. Clearing measurements from Active Memory does not affect Non-Volatile Memory.
NON-VOLATILE MEMORY
P01 P02 P03 P04 P05 P06 P07 P08 P09 P10
NON-VOLATILE MEMORY NOT ACCESSIBLE
Non-Volatile Memory is not affected by power state. Information is stored if power is on or off, with or without batteries.
CHANGING MEASUREMENT MODE WILL CLEAR ALL MEASUREMENTS STORED IN MEMORY.
The Measurement Mode determines how patient records are stored. If the Measurement Mode is changed, only Patient ID info is maintained.
OD/OS INFO
1. After measurements are taken, the results can be sent back to the PC, or directly to a Bluetooth® enabled printer.
Single Patient Mode is always available, however information can only be transferred to a PC if the device has a Bluetooth® module installed.

Fig 10.1.1 Single Patient Mode

10.2 Multi-Patient Mode

NOTE: Use of Multi-Patient Mode is only available with a Bluetooth® enabled device. This includes transferring data and storing data in memory.

Multi-Patient Mode allows the user to access the memory of the device for storing patient measurements. Multi-Patient mode is indicated by a number (P01-P20) being displayed in the bottom left-hand corner of the screen.



The memory is capable of storing information for 20 patients. The user selects a number (P01-P20) and takes measurements for the right and left eye. When measurement is complete, the user presses the CFG key and all results are recorded and can be retrieved at a later time.

The user can also use the DGH Connect Software (See section 15) to enter patient identification information before taking measurements.

NOTE: In Multi-Patient Mode the device can take either *Continuous Averaging* or *Mapping* measurements. However, if the *Measurement Mode* is changed it will clear the measurements, for all patients stored in memory.

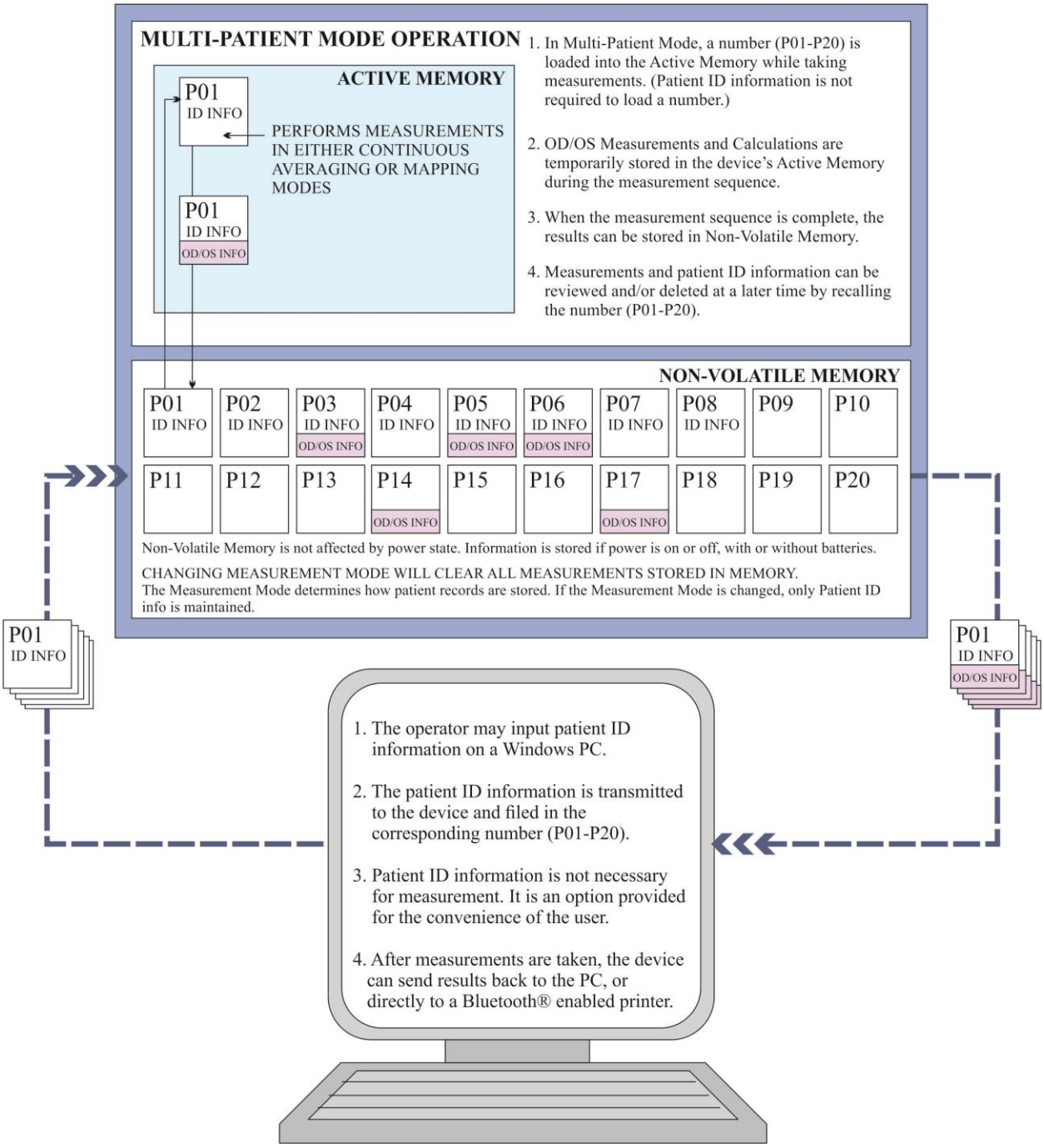

MULTI-PATIENT MODE OPERATION
1. In Multi-Patient Mode, a number (P01-P20) is loaded into the Active Memory while taking measurements. (Patient ID information is not required to load a number.)
2. OD/OS Measurements and Calculations are temporarily stored in the device's Active Memory during the measurement sequence.
3. When the measurement sequence is complete, the results can be stored in Non-Volatile Memory.
4. Measurements and patient ID information can be reviewed and/or deleted at a later time by recalling the number (P01-P20).
ACTIVE MEMORY
P01
ID INFO
PERFORMS MEASUREMENTS IN EITHER CONTINUOUS AVERAGING OR MAPPING MODES
P01
ID INFO
OD/OS INFO
NON-VOLATILE MEMORY
P01 ID INFO
P02 ID INFO
P03 ID INFO OD/OS INFO
P04 ID INFO
P05 ID INFO OD/OS INFO
P06 ID INFO OD/OS INFO
P07 ID INFO
P08 ID INFO
P09
P10
P11
P12
P13
P14 OD/OS INFO
P15
P16
P17 OD/OS INFO
P18
P19
P20
Non-Volatile Memory is not affected by power state. Information is stored if power is on or off, with or without batteries.
CHANGING MEASUREMENT MODE WILL CLEAR ALL MEASUREMENTS STORED IN MEMORY.
The Measurement Mode determines how patient records are stored. If the Measurement Mode is changed, only Patient ID info is maintained.
P01
ID INFO
P01
ID INFO
OD/OS INFO
1. The operator may input patient ID information on a Windows PC.
2. The patient ID information is transmitted to the device and filed in the corresponding number (P01-P20).
3. Patient ID information is not necessary for measurement. It is an option provided for the convenience of the user.
4. After measurements are taken, the device can send results back to the PC, or directly to a Bluetooth® enabled printer.

Fig 10.2.1 Multi-Patient Mode

10.3 Changing Patient Modes

10.3.1 By default, the **Pachette 4** is in Single Patient Mode upon power up. To confirm that the device is in Single Patient Mode, press the CFG key and the device will display the 'Select Patient' screen with '-- Single --' selected:

- If Single Patient Mode is preferred, press the CFG key to exit the menu.

10.3.2 Pressing the ▲ or ▼ key will scroll through the 'Select Patient' menu. Available patient locations are indicated by a number (P01-P20) on the bottom left-hand side of the screen.

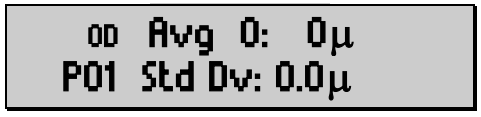
- If the patient location is empty, there will be a '--No Data--' message.

- If the patient location contains recorded measurements, there will be a '-Meas Only-' message.

- If the location contains patient ID information (See 15.5 for instruction on entering patient ID) the device will show the patient name. By pressing the OD or OS key while the patient's name is displayed, other identifying information will be displayed.

10.3.3 To select a patient location press the CFG key when the desired location number is displayed.

10.3.4 The device will then enter Measurement Mode and show a number in the bottom left-hand corner of the screen. The device is now ready to record measurements to the location.



10.3.5 After taking measurements (See section 12 for measurement instructions), press the CFG key to enter the Configuration Menu. The **Pachette 4** records the information to the specified location in Non-Volatile Memory once the CFG key is pressed.

10.3.6 To select a different patient location or Single Patient Mode, press the ▲ or ▼ key to scroll through the 'Select Patient' menu. Press the CFG key again to make the selection.

10.4 Adding Patient Identification Information

The **Pachette 4** will store a single patient's name, ID number, date of birth and gender in each patient location. Patient ID information is entered by connecting the **Pachette 4** to a computer using the optional Bluetooth® connection and utilizing the DGH Connect Software.

See section 14 regarding Bluetooth® connectivity, and section 15 regarding the use of DGH Connect Software.

10.5 Clearing Patient Information

10.5.1 Press the CLR key. The user will be prompted with the 'What To Clear?' menu:

- Use the ▲ or ▼ key to scroll through the clearing options. Press the ENT key to select an option.

- The following selections affect the patient currently being measured.
    - Selecting 'All Current Meas' clears all measurements of both the left and right eye for the currently loaded patient.
    - Selecting 'OD Current Meas' clears all measurements of the right eye for the currently loaded patient.
    - Selecting 'OS Current Meas' clears all measurements of the left eye for the currently loaded patient.
    - Selecting 'Nothing (Exit)' exits the menu without deleting anything.

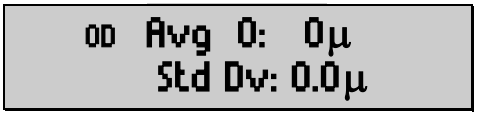
- The other clearing options affect stored patient information or system configuration.
    - Selecting 'All Patients' clears all identifying information and all measurements for all patients. (Bluetooth® option only)
    - Selecting 'Paired Devices' clears all paired devices from the device memory. (Bluetooth® option only)

11. Measurement Modes

The **Pachette 4** allows the user to select the preferred *Measurement Mode*. The device will either use *Continuous Averaging* or *Mapping* configuration when reporting measurements. It is important to note that switching between *Continuous Averaging* or *Mapping* will clear ALL measurements; this includes patient information stored in Non-Volatile Memory.

11.1 Continuous Averaging Measurement Mode

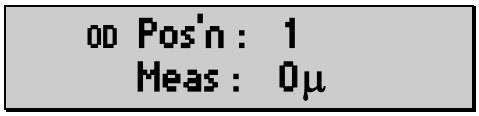
The **Pachette 4**'s factory-default *Measurement Mode* option is *Continuous Averaging*. In this mode the device takes 25 corneal measurements (in rapid succession) at a single location and generates an average from those measurements. The device allows the user to program how many measurements are taken (from 1 to 25), as well as the period of time between consecutive measurements (default is <50msec). While in *Continuous Averaging Measurement Mode* the screen will display which eye is being measured, the measurements and standard deviation.



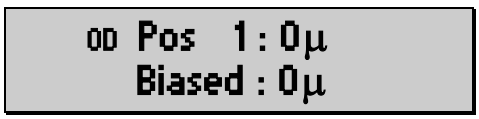
See section 13.2 for information on configuring *Continuous Averaging* parameters.
See section 12.2 for information on taking measurements in *Continuous Averaging Measurement Mode.*

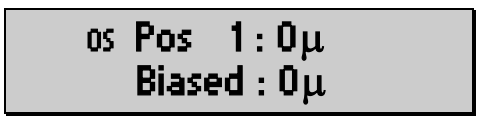
11.2 Mapping Measurement Mode

The **Pachette 4**'s other *Measurement Mode* option is *Mapping Mode.* In this mode the operator is able to take a single measurement (not averaged) at various positions on the cornea. While in Mapping Measurement Mode the screen will display which eye is being measured, the mapping position number and the measurement.



The device can also be configured to display an operator defined measurement bias while in *Mapping Measurement Mode*. (See section 13.3.2). When biased measurements are enabled, the screen will display which eye is being measured, the mapping position number, the actual measurement and the calculated biased measurement.





With *Mapping Measurement Mode* enabled, the **Pachette 4** can be programmed to record from 1 to 33 unique measurement positions. The illustration below shows 33 potential measurement points.

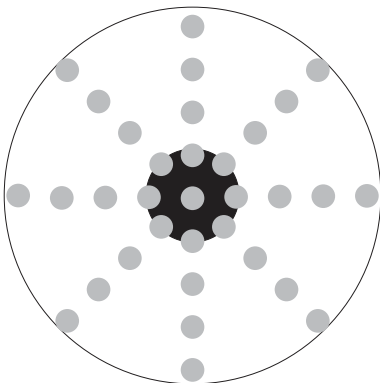


Fig 11.2.1 Potential Mapping Points

Using multiple measurement points allows the user to "map" the thicknesses of the cornea at various locations; however the operator must keep track of which measurement belongs to each corneal position. This can be achieved with the help of corneal thickness charts, which are available upon request from DGH Technology, Inc.

See section 13.3 for information on configuring *Mapping* parameters.
See section 12.3 for information on taking measurements in *Mapping Measurement Mode.*

11.3 Changing Measurement Modes

WARNING: All measurements in the device, including those stored in memory will be cleared when the *Measurement Mode* is changed. Check that all required data has been recorded outside of the device before changing the *Measurement Mode*.

11.3.1 Upon power-up the **Pachette 4**'s *Measurement Mode* will be set to the last setting used (factory default is *Continuous Averaging*).

11.3.2 To check the *Measurement Mode* setting, press the CFG key, and then repeatedly press the ENT key to scroll through the configuration options. Scroll until the 'Operational Mode' menu is displayed.

11.3.3 Pressing the ▲ or ▼ key will switch between *Continuous Averaging* or *Mapping* modes.

11.3.4 Press the CFG key when the preferred mode is displayed. If changes have been made, the device will display the 'Save New Config' message.

11.3.5 Press the ▲ key to select 'Yes' to save the configuration.

- If there is data that is cleared, the device will display the 'ALL MEAS CLEARED Config Saved' message.

- If there is no data to clear, the device will display the 'Saving New Config' message.

- After the message is displayed, the device will show the screen for the appropriate *Measurement Mode.*

12. Taking Measurements

The **Pachette 4** is shipped from the factory preset to *Continuous Averaging Measurement Mode*. The user can begin taking measurements immediately if this is the preferred mode.

The device is packaged with (2) AA batteries pre-installed and the probe cord wrapped around the cord wrap on the protective holster, with the probe seated in the protective cavity.

WARNING: In order to reduce the risk of infection, the DGH 555B must be cleaned and disinfected prior to each biometry procedure. Refer to section 17 for details.

12.1 Power Up Sequence

12.1.1 Remove the probe from the cavity by grasping the body of the probe at the access opening in the holster.

- It is recommended that the probe be returned to the cavity for protection when transporting the **Pachette 4**, or when the unit is not being used.

WARNING: Do not pull on the probe cord to remove the probe as this can cause damage to the probe.

12.1.2 Unwrap the probe cord. The probe connector may be removed from the holster cavity by gently pulling on the probe cord at the connector strain relief.

12.1.3 Carefully align probe connector for proper mating orientation and insert into the opening on the right side of the holster. See section 7.1 for connector orientation.

12.1.4 Gently press probe into opening until probe is properly mated. Inspect the probe tip to verify it is clean and free of any nicks, scratches or any other defect that could injure the cornea. (Refer to section 17.1 for Cleaning and Disinfecting Instructions)

12.1.5 Flip tilt stand away from holster and place unit on flat surface in tilted position.

12.1.6 Turn on the unit.

12.1.7 The **Pachette 4** performs an internal self-test function.

12.1.8 The unit will briefly display battery status as indicated:

12.1.9 When the power-up sequence is finished, the device automatically enters *Measurement Mode*. The device will start in the last *Measurement Mode* selected when powered off. The factory default is *Continuous Averaging Measurement Mode.*

12.1.10 The **Pachette 4** is now ready to take corneal measurements. If any default parameters need to be modified, refer to section 13. Otherwise, refer to sections 12.2 and 12.3 for detailed descriptions of the proper methods for obtaining measurements.

12.2 Measurement in Continuous Averaging Mode

NOTE: Typically, anesthetizing the patient's eye is necessary for obtaining a measurement.

12.2.1 Perform the Power Up Sequence as described in Section 12.1.

12.2.2 Press the CFG key to enter the Configuration Menu. Press the ENT key repeatedly to navigate through the menu.

12.2.3 Confirm that *Continuous Averaging Mode* is selected in the 'Operational Mode' menu. (See Section 11.3)

12.2.4 Select a memory location to associate measurements with, or select Single Patient Mode. (See Sections 10.1 and 10.2)

12.2.5 Select the number of measurements to be obtained (default is 25 measurements). (See Section 13.2.2)

12.2.6 Press the CFG key to exit the Configuration Menu. If changes have been made, the **Pachette 4** will prompt for confirmation of the configuration change.

12.2.7 Press the ▲ key to select 'Yes' and save the configuration. The **Pachette 4** will return to *Measurement Mode*.

12.2.8 Select the eye to be measured. You can select either eye for measurement by pressing the OD or OS key. The selected eye will be displayed in the upper left-hand corner. By default, the device is prepared to measure the RIGHT eye.

12.2.9 Have the patient visualize a fixation point.

12.2.10 Confirm that the device is in *Measurement Mode*. (The blinking black cursor is not shown in the upper left-hand corner).

12.2.11 Gently position the probe tip on the cornea as described in section 4.4. The **Pachette 4** will automatically begin the measurement cycle when the probe is properly applanated.

- The device will emit a quick 'beep' for each successful measurement.
- If the device is not able to obtain a measurement within 3 seconds, the device will emit a long beep and the 'Poor Applanation' message will be displayed.

- If the 'Poor Applanation' message is displayed, attempt to reposition the probe tip for proper applanation. Once the probe tip is in proper alignment, the device will continue measurement.

12.2.12 Once the device has collected the required number of measurements, the device will emit two long 'beeps' and display the 'Measurement Group Completed' message.

12.2.13 The device will display the measurement average and standard deviation of the eye measured. To scroll through individual measurements, press the ▲ or ▼ key.

- If 'Auto-Switching' is enabled (See 13.2.1), the device will only display the results for a few seconds before switching to the other eye for measurement.
- The example shows the right eye measurements. 'Avg 25' indicates 25 successful measurements, and the average of those measurements is 540 µm. The calculated standard deviation is 0.3µm.

- To scroll through each measurement, press the ▲ or ▼ key. The device will list the result of each measurement taken while showing the Standard Deviation on the bottom line.

12.2.14 If a questionable measurement is found during review, the operator can delete it. To do this, the operator presses the DEL key while viewing the measurement in question. The Measurement Average and Standard Deviation will be automatically updated.

- The operator can take new measurements to replace those that were deleted or choose to accept the remaining measurements.

12.2.15 Once both the OD and OS measurement groups are complete, no more measurements can be taken for that eye, unless the measurements of that group are cleared. (Or individual measurements are deleted, as described in 12.2.14)

12.2.16 If the device is operating in Multi-Patient Mode the measurements will be automatically saved to memory.

12.2.17 To clear all measurements for one or both eyes, press the CLR key. The user will be prompted with the 'What To Clear?' menu:

- The following selections affect the patient currently being measured.
    - Selecting 'All Current Meas' clears all measurements of both the left and right eye for the currently loaded patient.
    - Selecting 'OD Current Meas' clears all measurements of the right eye for the currently loaded patient.
    - Selecting 'OS Current Meas' clears all measurements of the left eye for the currently loaded patient.
    - Selecting 'Nothing (Exit)' exits the menu without deleting anything.

- The other clearing options affect stored patient information or system configuration.
    - Selecting 'All Patients' clears all identifying information and all measurements for all patients. (Bluetooth® option only)
    - Selecting 'Paired Devices' clears all paired devices from the device memory. (Bluetooth® option only)

12.3 Measurement in Mapping Mode

NOTE: Typically, anesthetizing the patient's eye is necessary for obtaining a measurement.

12.3.1 Perform the Power Up Sequence as described in Section 12.1.

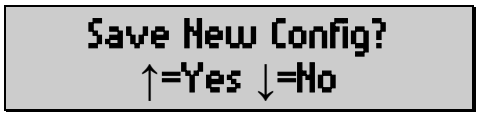
12.3.2 Press the CFG key to enter the Configuration Menu. Press the ENT key repeatedly to navigate through the menu.

12.3.3 Confirm that *Mapping Mode* is selected in the 'Operational Mode' menu. (See Section 11.3)

12.3.4 Select a memory location to associate measurements with, or select Single Patient Mode. (See Sections 10.1 and 10.2)

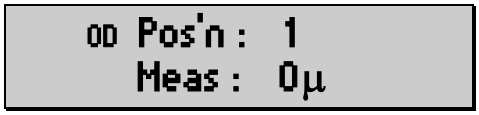
12.3.5 Select the number of positions to be measured (default is 33 measurements). (See Section 13.3.1)

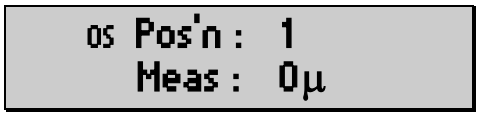
12.3.6 Press the CFG key to exit the Configuration Menu. If changes have been made, the **Pachette 4** will prompt for confirmation of the configuration change.



12.3.7 Press the ▲ key to select 'Yes' and save the configuration. The **Pachette 4** will return to *Measurement Mode*.

12.3.8 Select the eye to be measured. You can select either eye for measurement by pressing the OD or OS key. The selected eye will be displayed in the upper left-hand corner. By default, the device is prepared to measure the RIGHT eye.





- The device can also be configured to display an operator defined measurement bias while in *Mapping Measurement Mode*. (See sections 13.3.2 and 13.3.3)

12.3.9 Have the patient visualize a fixation point.

12.3.10 Confirm that the device is in *Measurement Mode*. (The blinking black cursor is not shown in the upper left-hand corner).

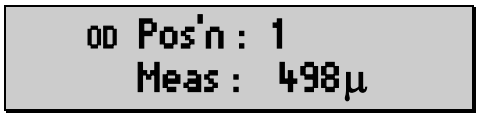
12.3.11 Gently position the probe tip on the cornea as described in section 4.4. The **Pachette 4** will automatically take a single measurement when the probe is properly applanated.

- For each successful measurement taken the device will emit a quick 'beep'.

- If the device is not able to obtain a measurement within 3 seconds, the device will emit a long beep and the 'Poor Applanation' message will be displayed.

- If the 'Poor Applanation' message is displayed, attempt to reposition the probe tip for proper applanation. Once the probe tip is in proper alignment, the device will continue measurement.

12.3.12 After each successful measurement the device will show the result on the display for a short time (Good Measurement Delay, default 2 seconds).



- During this time either wait for two short 'beeps' before re-applanating the probe at the next mapping position or:

- Re-applanate at the same point to re-measure that mapping position.

12.3.13 The device will emit two short 'beeps' when it is ready to take the measurement at the next mapping position. Reposition the probe and re-applanate at the next position to be mapped.

12.3.14 Continue measuring all positions until all necessary measurements have been taken.

12.3.15 The device DOES NOT indicate when all measurements have been taken; instead it will go back to the measurement for position number 1.

- To scroll through each measurement press the ▲ or ▼ key. The device will list the position number and list the thickness measurement below.

12.3.16 If a questionable measurement is found during review, the operator can delete it. To do this, the operator presses the DEL key while viewing the measurement in question.

- The operator can take new measurements to replace those that were deleted or choose to accept the remaining measurements.

12.3.17 If the device is operating in Multi-Patient Mode the measurements will be automatically saved to memory.

12.3.18 To clear all measurements for one or both eyes, press the CLR key. The user will be prompted with the 'What To Clear?' menu:

- The following selections affect the patient currently being measured.
    - Selecting 'All Current Meas' clears all measurements of both the left and right eye for the currently loaded patient.
    - Selecting 'OD Current Meas' clears all measurements of the right eye for the currently loaded patient.
    - Selecting 'OS Current Meas' clears all measurements of the left eye for the currently loaded patient.
    - Selecting 'Nothing (Exit)' exits the menu without deleting anything.

- The other clearing options affect stored patient information or system configuration.
    - Selecting 'All Patients' clears all identifying information and all measurements for all patients. (Bluetooth® option only)
    - Selecting 'Paired Devices' clears all paired devices from the device memory. (Bluetooth® option only)

12.4 Viewing Date and Time

The **Pachette 4** can display the time and date on the screen to assist the operator in recording when measurements are taken.

12.4.1 Press and hold the CLR key until the Time / Date screen is displayed.

12.4.2 The Time / Date screen will be displayed until the operator presses the CLR key again. The device will return to Measurement Mode.

- The user can configure how the date will be displayed. See section 13.4.7.

12.4.3 If the user is using a Bluetooth® enabled device to receive patient reports, the Time and Date will be recorded with the measurements.

13. Configuring the Pachette 4

When shipped from the factory, the **Pachette 4** is ready to take corneal measurements. No additional setup or configuration is necessary. However, the **Pachette 4** has been designed to allow the operator to modify certain parameters to tailor the instrument to meet one's needs. Once modified, these parameters are permanently stored in non-volatile memory and are automatically recalled each time the unit is powered up. To change a parameter, the operator must access the configuration menu. The following procedure explains how to access the configuration menu and modify the default parameters.

13.1 Entering and Navigating the Configuration Menu

13.1.1 To enter the Configuration Menu, press the CFG Key. The screen will display:

13.1.2 While in the Configuration Menu, each time that the ENT key is pressed the device will display the next editable parameter. When the last parameter is reached and the ENT key is pressed, the device will re-start the list.

13.1.3 To change a parameter setting, use the ▲, ▼, OD or OS keys as indicated in the table below.

13.1.4 After all necessary changes have been made, press the CFG key again.

13.1.5 If changes have been made, the 'Save New Config?' message will appear. Select 'Yes' or 'No' as appropriate.

The following table shows all device parameters, in the order that they are displayed in the list.

NOTE: Shaded parameters in this table are only available when certain settings are active, e.g. *Continuous Averaging* parameters are only editable when *Continuous Averaging* is enabled.

Configuration Menu Parameters

Press the CFG key: **Enter the Configuration Menu**
Press the ENT key repeatedly: **Navigate down the Parameters List**
Press the CFG key again: **Exit the Configuration Menu**

Parameter Availability	Parameter [default value]	Changing A Setting	Range	Result/Description
Always available	**Select Patient [-- Single --]**	Press ↑ or ↓ key to navigate through patient files	-- Single --	The device will clear measurements when the user initiates a new measurement cycle.
			P1 to P20	Each number indicates a memory location. Patient measurements will be stored in non-volatile memory
Always available	**Bluetooth [On]**	Press ↑ or ↓ key to turn Bluetooth® module on or off.	Off	The Bluetooth® module is turned off.
			On	The Bluetooth® module is turned on
Only available if Bluetooth® is enabled.	**Send Meas To**	Press ↑ or ↓ key to switch between linked devices. Press OD to send data	Will display up to 5 linked devices	The user selects the device using the ↑ or ↓ keys. When the OD button is pressed, the device sends the data.
Only available if Bluetooth® is enabled.	**Add PC/Printer**	Press OD key to initiate a scan	Not Scanning	While the 'Add PC/Printer' menu is visible, the device will be discovered when scanned by other Bluetooth® enabled devices
			Scanning	When the OD key is pressed, the device is actively scanning for other Bluetooth® enabled devices.
Only available if Bluetooth® is enabled.	**Printer Config**	Press ↑ or ↓ key to switch between printer config options. Then press the OD key to select what to include	Add Patient	When 'Y' (Yes) is displayed, patient information will be included on the printout.
			Add Notes	When 'Y' (Yes) is displayed, operator notes will be included on the printout.
			Add All Meas	When 'Y' (Yes) is displayed, all measurements will be included on the printout.
Always available	**Operational Mode [Continuous Ave]**	Press ↑ or ↓ key to switch between Continuous Ave and Mapping.	Continuous Ave	The device is in Continuous Averaging Mode
			Mapping	The device is in Mapping mode
Always available	**Auto Switch OD/OS [Enabled]**	Press ↑ or ↓ key to enable or disable Auto Switch	Disabled	The device WILL NOT automatically switch eyes when measurements are finished for an eye in Continuous Averaging Mode
			Enabled	The device WILL automatically switch eyes when measurements are finished for an eye in Continuous Averaging Mode
Only available if in Continuous Ave Mode	**Numb Of Meas [25]**	Press ↑ or ↓ key to change the value	1 to 25	The device will take this number of measurements at single position
Only available if in Continuous Ave Mode	**Auto Rep Delay [<50]**	Press ↑ or ↓ key to change the value	<50 to 950	The period of time (in milliseconds) between measurements while the probe is applanated to the cornea.
Only available if in Mapping Mode	**Numb of Posn [33]**	Press ↑ or ↓ key to change the value	1 to 33	Selects the number of positions to be measured for each eye. One measurement per position.

Configuration Menu Parameters

Press the CFG key: **Enter the Configuration Menu**
Press the ENT key repeatedly: **Navigate down the Parameters List**
Press the CFG key again: **Exit the Configuration Menu**

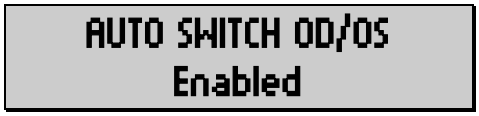
Parameter Availability	Parameter [default value]	Changing A Setting	Range	Result/Description
Only available if in Mapping Mode	**Disp Bias Meas [Enabled]**	Press ↑ or ↓ key to enable or disable	Disabled	The device WILL NOT display measurement bias while in Mapping Mode
			Enabled	The device WILL display measurement bias while in Mapping Mode
Only available if in Mapping Mode and Disp Bias is enabled	**Amount Of Bias [100%]**	Press ↑ or ↓ key to change the value	1% to 199%	Selects the percentage to calculate biased measurements
Only available if in Mapping Mode	**Good Meas Delay [1.0 sec]**	Press ↑ or ↓ key to change the value	1.0 to 9.5	Period of time (in seconds) after a measurement that the device will display the result before advancing to the next measurement position
Only available if in Mapping Mode	**Poor Appl Delay [2.0 sec]**	Press ↑ or ↓ key to change the value	1.0 to 9.5	Period of time (in seconds) after a poor applanation occurs before the unit will automatically advance to the next measurement position
Always Available	**Delay to Standby [1.0 min]**	Press ↑ or ↓ key to change the value	0.5 to 9.5	Period of time (in minutes) that the device will wait before automatically switching to Standby Mode
Always Available	**Battery Type [Rechargeable]**	Press ↑ or ↓ key to change the value	Alkaline	The device is set to monitor voltages for alkaline batteries.
			Rechargeable	The device is set to monitor voltages for rechargeable batteries.
Always Available	**Back Light [Off in Standby]**	Press ↑ or ↓ key to change the value	Off in Standby	The back light will turn off in Standby Mode or when in the configuration menu.
			Off	The back light is always off.
			On	The back light is always on.
Always Available	**Brightness [7 segments]**	Press ↑ or ↓ key to change the value	1 to 14 (segments)	Adjusts display brightness for desired viewing.
Always Available	**Contrast [7 segments]**	Press ↑ or ↓ key to change the value	1 to 14 (segments)	Adjusts display contrast for desired viewing.
Always Available	**Volume [7 segments]**	Press ↑ or ↓ key to change the value	1 to 14 (segments)	Adjusts alarm volume to desired level.
Always Available	**Date / Time**	Press OS to Format Press OD to Set	Format	Use the ↑ or ↓ key to select either MMM-DD-YYYY or DD-MMM-YYYY. The device will display the date in this format.
			Set	Use the OD or OS keys to move the cursor left or right. Use the ↑ or ↓ key to change the values. This will set the date and time for the device. Date and time must be reset after batteries are changed.

13.2 Parameters for Continuous Averaging Measurement Mode

These are the *Continuous Averaging Measurement Mode* parameters that are accessible from the Configuration Menu. The device must be set to *Continuous Averaging* to access these parameters.

NOTE: To access these parameters, enter the Configuration Menu by pressing the CFG key. Press the ENT key repeatedly to navigate through the menu. See section 13.1

13.2.1 Auto Switch (default enabled) can be enabled or disabled for *Continuous Averaging Mode*. With Auto Switch enabled, the device will automatically switch eyes (after a 4 second delay) when a measurement group is complete. Press the ▲ or ▼ key to change the configuration.



13.2.2 Numb of Meas (default 25) is the number of measurements that the unit will use to calculate the measurement average and standard deviation of a measurement point in *Continuous Averaging Measurement Mode.* It can be adjusted from 1 to 25. Press the ▲ or ▼ key to change the value.

⚠ **WARNING:** All measurements in the device, including those in memory will be cleared when the Number of Measurements is changed.

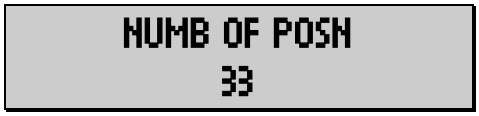
13.2.3 Auto Rep Delay (default <50 msec) is the period of time (in milliseconds) that the device will wait between consecutive measurements while the probe is applanated to the cornea in *Continuous Averaging Measurement Mode.* It can be adjusted from <50 msec to 950msec. Press the ▲ or ▼ key to change the value.

13.3 Parameters for Mapping Measurement Mode

These are the *Mapping Measurement Mode* parameters that are accessible from the Configuration Menu. The device must be set to *Mapping* to access these parameters.

NOTE: To access these parameters, enter the Configuration Menu by pressing the CFG key. Press the ENT key repeatedly to navigate through the menu. See section 13.1

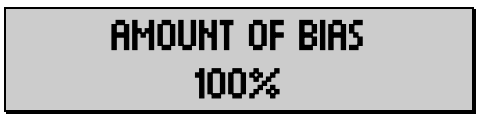
13.3.1 Numb of Posn (default is 33) is the number of positions where the device will take single measurements. It can be adjusted from 1 to 33. Press the ▲ or ▼ key to change the value.



WARNING: All measurements in the device, including those in memory will be cleared when the Number of Positions is changed.

13.3.2 Disp Bias Meas (default disabled) enables or disables if the device will display a measurement bias with each measurement taken during *Mapping Measurement Mode.* Press the ▲ or ▼ key to change the configuration

13.3.3 Amount Of Bias (default 100%) determines the amount of bias used in calculating the measurement bias in *Mapping Measurement Mode.* This parameter is only available if the device is configured to display measurement bias. It can be adjusted from 1% to 199%. Press the ▲ or ▼ key to change the value.



- The amount of bias is applied to all patients stored in the device memory. If the amount of bias is changed, the device will re-calculate all bias measurements for all stored patients.

13.3.4 Good Meas Delay (default 1.0 sec) is the amount of time that the device will wait before advancing to the next mapping point after a measurement is taken. It can be adjusted from 1.0 sec to 9.5 sec. Press the ▲ or ▼ key to change the value.

13.3.5 Poor Appl Delay (default 2.0 sec) is the amount of time that the device will wait before advancing to the next mapping point after a poor applanation. It can be adjusted from 1.0 sec to 9.5 sec. Press the ▲ or ▼ key to change the value.

13.4 General Device Parameters

These are the general device parameters that are accessible from the Configuration Menu. They are accessible at any time.

NOTE: To access these parameters, enter the Configuration Menu by pressing the CFG key. Press the ENT key repeatedly to navigate through the menu. See section 13.1

13.4.1 Delay To Standby (default 1.0 min) is the amount of time that the device will wait before going into Standby Mode. It can be adjusted from 0.5 min to 9.5 min. Press the ▲ or ▼ key to change the value.

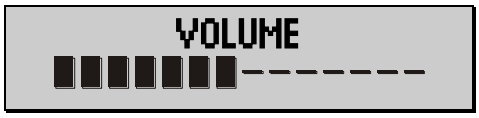
13.4.2 Battery Type should be selected to match the batteries installed in the device. If the device detects that the batteries have been removed, a prompt will require the user to set the battery type accordingly (see section 16.2.6). Press the ▲ or ▼ key to change the value.

13.4.3 Back Light (default Off in Standby) determines how the backlight of the screen will function. It can be set to always On, always Off, or Off in Standby mode. Press the ▲ or ▼ key to change the value.

13.4.4 Brightness (default 7 bars) determines the brightness of the backlight. Press the ▲ or ▼ key to change the value.

13.4.5 Contrast (default 7 bars) determines the contrast of the screen. Press the ▲ or ▼ key to change the value.

13.4.6 Volume (default 7 bars) determines the volume of audible signals/alarms. Press the ▲ or ▼ key to change the value.



13.4.7 Time/Date allows the user to set the time and date and choose the date format. Press the OS key to adjust the date format. Press the OD key to set the time.

- Press the OS key to enter the **Date Format** (default MMM-DD-YYY) sub-menu. Press the ▲ or ▼ key to change the value. The date can display as either MMM-DD-YYYY or DD-MMM-YYYY.

- Press the OD key to enter the **Time Date** sub-menu. While in this sub-menu there will be a blinking black cursor. Use the OD and OS keys to move the cursor left and right. Press the ▲ or ▼ key to change the value in each field.

13.5 Bluetooth® Parameters

These are the Bluetooth® operation parameters. If the **Pachette 4** has a Bluetooth® module installed, they will be accessible when the Bluetooth® parameter is enabled. Only Devices with a Bluetooth® Wireless Technology Logo printed on the front have a module installed.

NOTE: To access these parameters, enter the Configuration Menu by pressing the CFG key. Press the ENT key repeatedly to navigate through the menu. See section 13.1

13.5.1 Bluetooth (default On) determines if the Bluetooth® module is enabled or disabled. This must be set to 'On' to connect devices or transfer files. Press the ▲ or ▼ key to change the value.

- When the Bluetooth® wireless module is enabled, a logo will appear in the upper left-hand corner.

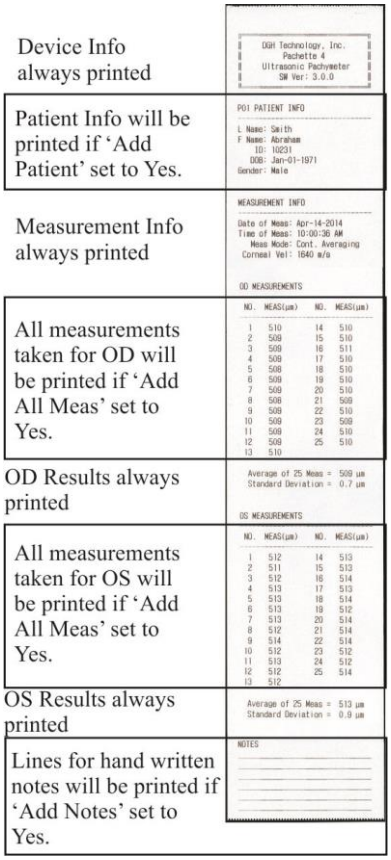
13.5.2 Send Meas To determines which device the **Pachette 4** will transmit records to. If there are no devices paired with the **Pachette 4**, the screen will display '---None---'.

- If the **Pachette 4** is paired to one or more devices, the screen will display:

  - NAME is the name of the device that will receive the records.
  - #**A** is the list number of the device shown.
  - #**B** is the total number of devices paired with the **Pachette 4**. Up to 5 devices can be paired at a time.
  - Send → indicates that pressing the OD key will cause the **Pachette 4** to transmit measurements to the currently displayed device.

13.5.3 When **Add PC/Printer** is displayed, the device is in Bluetooth® discoverable mode. This is a necessary mode for pairing Bluetooth® devices. See section 14 for information on device pairing.

13.5.4 Printer Config determines what information is sent to the Bluetooth® enabled printer. There are 3 fields that determine what is being sent. Press the ▲ or ▼ key to change the field.


Device Info always printed
DGH Technology, Inc.
Pachette 4
Ultrasonic Pachymeter
SW Ver: 3.0.0
Patient Info will be printed if 'Add Patient' set to Yes.
P01 PATIENT INFO
L Name: Smith
F Name: Abraham
ID: 10231
DOB: Jan-01-1971
Gender: Male
Measurement Info always printed
MEASUREMENT INFO
Date of Meas: Apr-14-2014
Time of Meas: 10:00:36 AM
Meas Mode: Cont. Averaging
Corneal Vel: 1640 m/s
OD MEASUREMENTS
NO. MEAS(µm) NO. MEAS(µm)
1 510 14 510
2 509 15 510
3 509 16 511
4 509 17 510
5 508 18 510
6 509 19 510
7 509 20 510
8 508 21 509
9 509 22 510
10 509 23 509
11 509 24 510
12 509 25 510
13 510
All measurements taken for OD will be printed if 'Add All Meas' set to Yes.
OD Results always printed
Average of 25 Meas = 509 µm
Standard Deviation = 0.7 µm
OS MEASUREMENTS
NO. MEAS(µm) NO. MEAS(µm)
1 512 14 513
2 511 15 513
3 512 16 514
4 513 17 513
5 513 18 514
6 513 19 512
7 513 20 514
8 512 21 514
9 514 22 514
10 512 23 512
11 513 24 512
12 512 25 514
13 512
All measurements taken for OS will be printed if 'Add All Meas' set to Yes.
OS Results always printed
Average of 25 Meas = 513 µm
Standard Deviation = 0.9 µm
NOTES
Lines for hand written notes will be printed if 'Add Notes' set to Yes.

- **Add Patient** (default Yes) field determines if patient name, ID number, date of birth and gender are included on the printed measurement report. Press the OD key to switch between Yes and No.

  - If 'Add Patient' is enabled, but no patient identifying information is entered, blank lines will be printed for hand-written notes.

- **Add Notes** (default No) determines if the printed measurement report will include an area for the operator's hand-written comments. Press the OD key to switch between Yes and No.

- **Add All Meas** (default No) determines if each measurement taken during *Continuous Averaging Mode* is printed, or only the average and standard deviation. Press the OD key to switch between Yes and No.

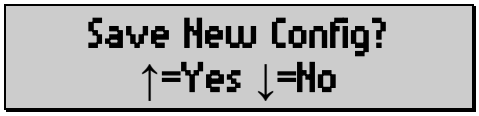
14. Configuring Bluetooth® Connections

Bluetooth® wireless features can only be enabled if your device has an optional Bluetooth® module installed. Only Devices with a Bluetooth® Wireless Technology Logo printed on the front (in the bottom left-hand corner) have a module installed.

14.1 Enabling Bluetooth®

14.1.1 To turn on the Bluetooth® wireless module, press the CFG key, then press the ENT one time to navigate to the Bluetooth parameter and set it to 'On' using the ▲ or ▼ key.

14.1.2 Press the CFG key to exit the Configuration menu and press the ▲ key to select 'Yes' when prompted to save the configuration. The **Pachette 4** will return to *Measurement Mode.*



14.1.3 An icon will appear in the upper left-hand corner to indicate that the Bluetooth® module is enabled.

14.2 Pairing with a Bluetooth® enabled printer

The **Pachette 4** can be paired directly to a Bluetooth® enabled printer. Once paired, the operator can print measurements directly from the device, without the need for a PC.

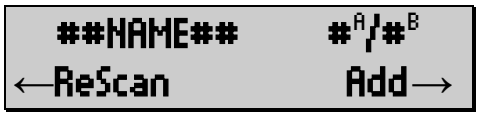
14.2.1 Turn on the printer and put it in the discoverable mode. Refer to the printer's user manual for instructions on using the printer's Bluetooth® features.

14.2.2 Turn on the **Pachette 4** and enter the Configuration Menu by pressing the CFG key.

14.2.3 Press the ENT key one time to navigate to the 'Bluetooth' parameter. Confirm that it is turned 'On'. If not, press the ▲ or ▼ key to enable Bluetooth. (See Section 14.1)

14.2.4 Press the ENT key two more times to navigate to 'Add PC/Printer' parameter. Press the OD button to initiate a scan. The scan may take up to a minute.

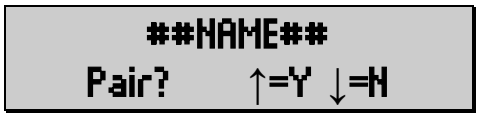
14.2.5 The **Pachette 4** will populate a list of all discovered Bluetooth® devices. Use the ▲ and ▼ keys to scroll through the list of available devices.



- NAME is the name of the device discovered.
- #**A** is the list number of the device shown.
- #**B** is the total number of devices discovered. Up to 5 devices can be discovered at a time.
- ←ReScan indicates that pressing the OS key will cause the **Pachette 4** to re-scan for devices.
- Add → indicates that pressing the OD key will cause the **Pachette 4** to attempt to pair with the displayed device.

14.2.6 With the desired device displayed, select 'Add' by pressing the OD key.

14.2.7 The **Pachette 4** will prompt the operator to confirm the device being paired to. Use the ▲ key to select 'Yes' when prompted.



14.2.8 The **Pachette 4** will display a message indicating that it is in the process of pairing. It will then prompt the user for the printer's Pin Code.

14.2.9 The **Pachette 4** will display 'Enter Pin Code' and show a blinking black cursor. Use the OS and OD keys to move the cursor left and right. Use the ▲ and ▼ keys to change the value.

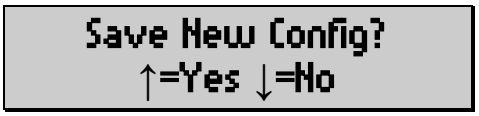
- The necessary Pin Code is provided with the printer. Typically the manufacturer will include the Pin Code in the user documentation.

14.2.10 Enter the Pin Code for the selected printer and press the ENT key.

14.2.11 A message will appear to indicate that the devices have been properly paired.

- The **Pachette 4** may briefly display the messages 'Bluetooth Connected' then 'Bluetooth Disconnected'. The pairing is still complete. The devices will re-connect automatically when measurements are sent to the printer.

14.2.12 The **Pachette 4** has now saved the pairing to memory. Press the CFG key to exit the Configuration Menu. The **Pachette 4** will prompt for confirmation of the configuration change.



14.2.13 Press the ▲ key to select 'Yes' and save the configuration. The **Pachette 4** will return to *Measurement Mode*.

14.3 Sending measurements to a Bluetooth® enabled wireless printer

14.3.1 Press the CFG key to enter the Configuration Menu and navigate to the 'Printer Config' menu by repeatedly pressing the ENT key.

14.3.2 Confirm that the desired fields are set to be included in the printed report. See section 13.5.4 for detailed instructions regarding printed fields.

14.3.3 Exit the Configuration Menu by pressing the CFG key. If changes have been made, the **Pachette 4** will prompt for confirmation of the configuration change.

14.3.4 Press the ▲ key to select 'Yes' and save the configuration. The **Pachette 4** will return to *Measurement Mode*.

14.3.5 Press and hold the ENT key until the **Pachette 4** displays the "Connecting to BT Device'. Printing will begin automatically.

- When printing in Single Patient Mode, only the Single Patient information will be printed. The measurements will be retained until cleared by the user or until Measurement Mode or Patient Mode is changed.

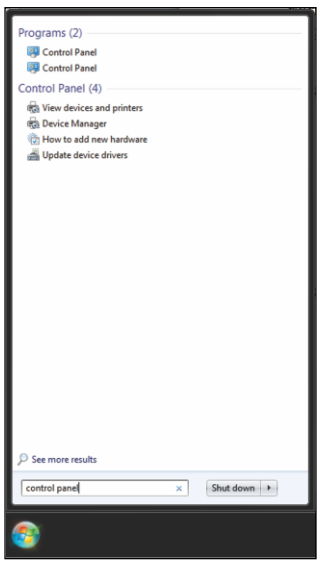
- When printing in Multi Patient Mode, all patient measurements in Non-Volatile Memory will be printed. The measurements will be retained until cleared by the user or until the Measurement Mode is changed.

14.3.6 The **Pachette 4** will store the printer configuration. This allows the user to print from this device directly at any time by pressing and holding the ENT key.

14.4 Pairing with a Bluetooth® enabled PC

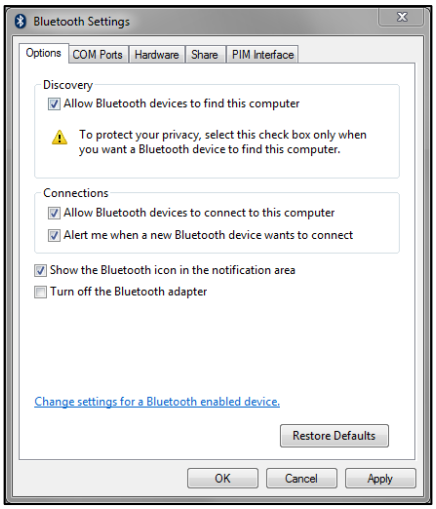
The **Pachette 4** can be paired with PCs that are equipped with Bluetooth® wireless technology. This can be via integrated Bluetooth® modules or USB adapters/dongles. Once the **Pachette 4** is properly paired with the PC, the operator can use the DGH Connect Software to input patient information and retrieve measurement reports.

14.4.1 Navigate to the Windows Control Panel by going to the Start menu and type 'Control Panel' in the search bar. The Start menu will list the Control Panel item. Click the list item to open the Control Panel. Find the 'Bluetooth Settings' item and click it to open the dialog box.



- Depending on the version of the operating system, the Start Menu may appear differently.

14.4.2 In ‘Bluetooth Settings’, under the ‘Options’ tab, enable the following features:


Bluetooth Settings
Options
COM Ports
Hardware
Share
PIM Interface
Discovery
Allow Bluetooth devices to find this computer
To protect your privacy, select this check box only when you want a Bluetooth device to find this computer.
Connections
Allow Bluetooth devices to connect to this computer
Alert me when a new Bluetooth device wants to connect
Show the Bluetooth icon in the notification area
Turn off the Bluetooth adapter
Change settings for a Bluetooth enabled device.
Restore Defaults
OK
Cancel
Apply

- Check the box for ‘Allow Bluetooth devices to find this computer’.
- Check the box for ‘Allow Bluetooth devices to connect to this computer’.
- Check the box for ‘Alert me when a new Bluetooth device wants to connect’.
- Check the box for ‘Show the Bluetooth icon in the notification area’.
- Depending on the version of the operating system, or the Bluetooth® software installed, the ‘Bluetooth Settings’ dialog box may appear differently.

14.4.3 Click the ‘Apply’ button then the ‘OK’ button.

14.4.4 Turn on the **Pachette 4** and enter the Configuration Menu by pressing the CFG key.

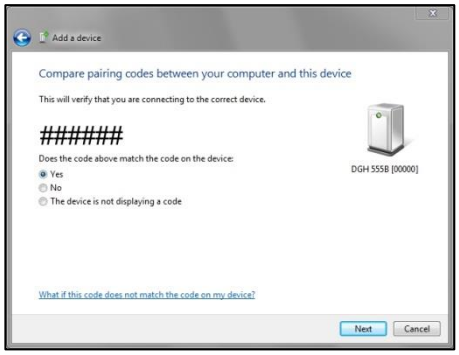
14.4.5 Press the ENT key one time to navigate to the ‘Bluetooth’ parameter. Confirm that it is turned ‘On’. If not, press the ▲ or ▼ key to enable Bluetooth. (See section 13.5.1)

14.4.6 Press the ENT key two times to navigate to ‘Add PC/Printer’ parameter. This screen indicates that the device is discoverable. Press the OD key to initiate a scan.

14.4.7 Once the scan is complete, use the ▲ or ▼ key to scroll through the available devices. With the PC you wish to pair with displayed, select ‘Add’.

- If the PC to be paired is not listed, press the OS key to re-scan.

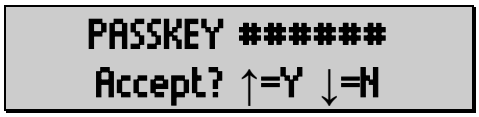
14.4.8 Both the **Pachette 4** and Windows will display a screen requiring confirmation of a passkey.


Add a device
Compare pairing codes between your computer and this device
This will verify that you are connecting to the correct device.
######
Does the code above match the code on the device:
Yes
No
The device is not displaying a code
DGH 555B [00000]
What if this code does not match the code on my device?
Next
Cancel

14.4.9 When Windows displays the passkey, select 'Yes' and click the 'Next' button.

- The passkey must be accepted on both devices within 30 seconds or a timeout error is produced.

14.4.10 When the **Pachette 4** displays the passkey, press the ▲ key to accept.



14.4.11 Pairing is now complete. Both Windows and the **Pachette 4** will display a message indicating that the process was completed.

Add a device
This device has been successfully added to this computer
Windows is now checking for drivers and will install them if necessary. You may need to wait for this to finish before your device is ready to use.
To verify if this device finished installing properly, look for it in Devices and Printers.
DGH 555B [00000]
Close

- After pairing, newer versions of Windows will automatically configure COM Ports. This may be indicated by a 'Driver Software Installation' message. Older versions of Windows may require the user to manually configure COM Ports (see section 14.5)

14.4.12 Press the CFG key on the **Pachette 4** to exit the configuration menu.

14.5 Adding COM Ports

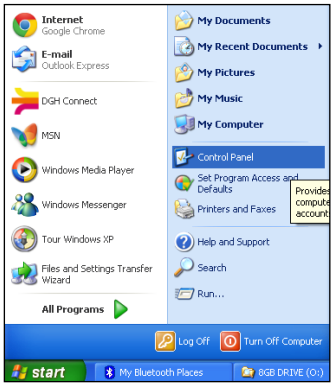
NOTE: Newer version of Windows automatically configure COM Ports when a device is paired, however the user may need to manually configure COM Ports in older versions of Windows. This process may vary depending on the hardware and software installed in the system.

NOTE: Depending on the software, the terms Serial Port and COM Port may be used interchangeably.

14.5.1 These steps are to be performed after the device has been paired with the PC. See section 14.4 for information on pairing to the PC.

14.5.2 Navigate to the Windows Control Panel by going to the Start menu and click on the 'Control Panel' item. Find the 'Bluetooth Settings' item and click it to open the dialog box.

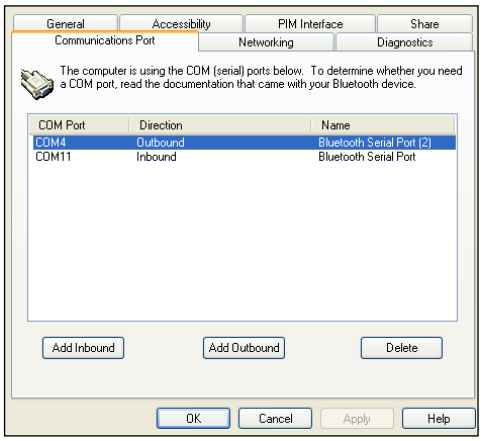
- Illustration shows the Windows XP Start Menu. Start menu will vary by operating system.



14.5.3 In the 'Bluetooth Settings' window there will typically be a tab indicating COM Port, Communications Port or Serial Port settings. Select this tab.

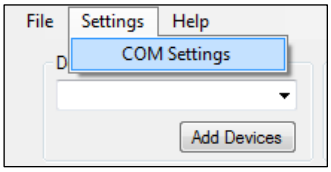
14.5.4 The DGH Connect software needs an 'Inbound' and 'Outbound' port to operate. If either is missing, add the appropriate port.

- Adding ports menu will vary depending on the software installed.



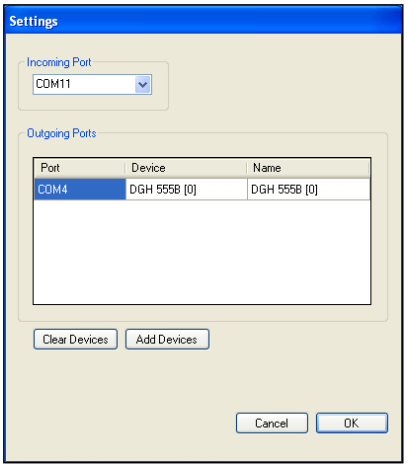
14.5.5 After the COM Ports have been set, start the DGH Connect software. If the software has not yet been installed, install it (section 15) and then complete the final steps.

14.5.6 In the DGH Connect software, navigate to Settings → COM Settings.



14.5.7 In the COM Settings dialog box, click the 'Add Devices' button. The Incoming Port and Outgoing Port should be automatically selected. Confirm that the COM Ports selected match the port numbers that were added in the 'Bluetooth Settings' menu.

- If the Incoming Port is incorrect, change it using the drop-down menu.



14.6 Sending and receiving information via Bluetooth® connection to a PC

The **Pachette 4** is capable of transmitting measurements and patient information via Bluetooth® wireless connections. However, the **Pachette 4** can only interact with PCs using the DGH Connect Software. Refer to section 15 for instructions on sending, receiving and printing reports using the DGH Connect Software on a PC.

14.7 Recalling paired device configuration

The **Pachette 4** will store pairing configurations for up to 5 devices. This allows for quick pairing at a later time. To recall a paired device:

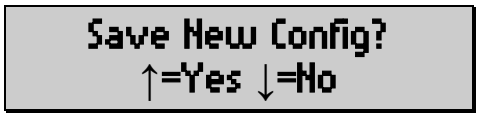
14.7.1 Enter the Configuration Menu by pressing the CFG key.

14.7.2 Press the ENT key one time to navigate to the 'Bluetooth' parameter. Confirm that it is turned 'On'. If not, press the ▲ or ▼ key to enable Bluetooth. (See Section 13.5.1)

14.7.3 Press the ENT one more time to navigate to 'Send Meas To' parameter. Use the ▲ and ▼ keys to scroll through the saved configurations.

- NAME is the name of the device that will receive the records.
- #^{A} is the list number of the device shown.
- #^{B} is the total number of devices paired with the **Pachette 4**. Up to 5 devices can be paired at a time.
- Send → indicates that pressing the OD key will cause the **Pachette 4** to transmit measurements to the currently displayed device.

14.7.4 With the desired device displayed, press the CFG key. The **Pachette 4** will prompt for confirmation of the configuration change.



14.7.5 Select 'Yes' by pressing the ▲ key. The **Pachette 4** is now configured to send measurements to the selected device.

14.8 Clearing A Single Paired Bluetooth® Device

Occasionally it may be necessary to clear a single Bluetooth® pairing setting from the **Pachette 4**'s memory to allow connection to new devices.

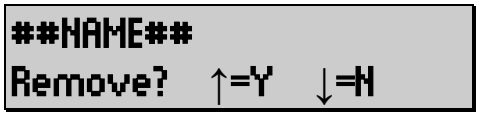
14.8.1 Enter the Configuration Menu by pressing the CFG key.

14.8.2 Press the ENT key one time to navigate to the 'Bluetooth' parameter. Confirm that it is turned 'On'. If not, press the ▲ or ▼ key to enable Bluetooth. (See Section 13.5.1)

14.8.3 Press the ENT two more times to navigate to 'Add PC/Printer' parameter. Press the OD key to initiate a scan.

14.8.4 The **Pachette 4** will populate a list of all discovered Bluetooth® devices. Use the ▲ and ▼ keys to scroll through the list of available devices. If the device is paired with the **Pachmate 2**, the message 'Paired →' will be displayed.

14.8.5 Press the OD key. The device will show the name of the paired device and give the option to remove it. Press the ▲ key to select yes. The device pairing has been removed.



14.8.6 Press the CFG key to return to Measurement Mode.

14.9 Clearing All Paired Bluetooth® Devices

Occasionally it may be necessary to clear Bluetooth® pairing settings from the **Pachette 4**'s memory to allow connection to new devices.

14.9.1 Press the CLR key. The user will be prompted with the 'What To Clear?' menu. Use the ▲ or ▼ key to scroll through the clearing options until 'Paired Devices' is displayed.

14.9.2 With 'Paired Devices' displayed, press the ENT key. The **Pachette 4** will clear all Bluetooth® devices pairing information from memory and display the 'Paired Devices List Cleared' message.

14.9.3 The **Pachette 4** will return to *Measurement Mode*.

15. DGH Connect Software

The DGH Connect Software is an application that allows the operator to use a Windows-based PC to communicate with DGH devices. This software will interact with **Pachette 4** and **Pachmate 2** devices.

To utilize DGH Connect, the PC must first be paired with the **Pachette 4**. For information on pairing refer to section 14.4.

15.1 Software Requirements

15.1.1 System Requirements

- Processor: 32-bit or 64-bit, 2 GHz
- Memory: 2 GB RAM
- Hard Drive: 1 GB minimum, 100 GB recommended
- Ports: USB 2.0
- Display: 1024 x 768 resolution
- Peripherals: Mouse (or Touchpad), Keyboard
- Bluetooth® Radio: v2.1 or later*

* Software is compatible with USB Bluetooth® adapters/dongles for desktop systems.

15.1.2 Compatible Operating Systems

- Microsoft Windows XP, Service Pack 3 or higher (32-bit)
- Microsoft Windows Vista, Service Pack 2 or higher (32-bit or 64-bit)
- Microsoft Windows 7 (32-bit or 64-bit)
- Microsoft Windows 8/8.1 (32-bit or 64-bit)

⚠ **WARNING:** Using "Non-Essential" software in conjunction with the DGH Connect software could have unknown / adverse Impact on the operation of the software and is therefore not recommended.

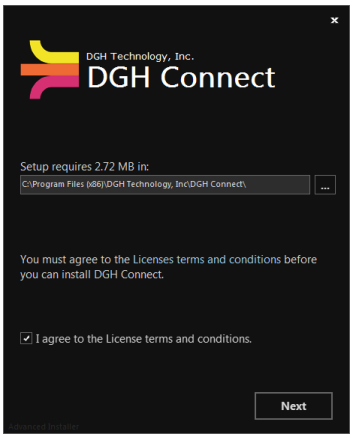
⚠ **WARNING:** Due to the threat of computer viruses, it is recommended that an anti-virus program be installed on the computer running the DGH Connect software.

15.2 Installing the software

15.2.1 Insert the USB flash drive and allow the computer to initiate the installation program.

15.2.2 The installer will check if the system has the .NET Framework v4.0. If the PC does not have this software installed, a dialog box will prompt for installation.

15.2.3 After the .NET Framework v4.0 has been installed, a dialog box will open indicating showing an installation directory. Confirm the installation directory, or set a custom directory.


DGH Technology, Inc.
DGH Connect
Setup requires 2.72 MB in:
C:\Program Files (x86)\DGH Technology, Inc\DGH Connect\
...
You must agree to the Licenses terms and conditions before you can install DGH Connect.
I agree to the License terms and conditions.
Next

15.2.4 Check the 'I Agree to the License terms and conditions' box on the bottom left-hand side of the window. The "Next" button will appear highlighted. Click the 'Next' button.

15.2.5 The software will list all necessary prerequisite programs.

15.2.6 The installer will then install the remaining prerequisites:

- Microsoft® System CLR Types for SQL Server® 2012
- Microsoft Report Viewer 2012 Runtime

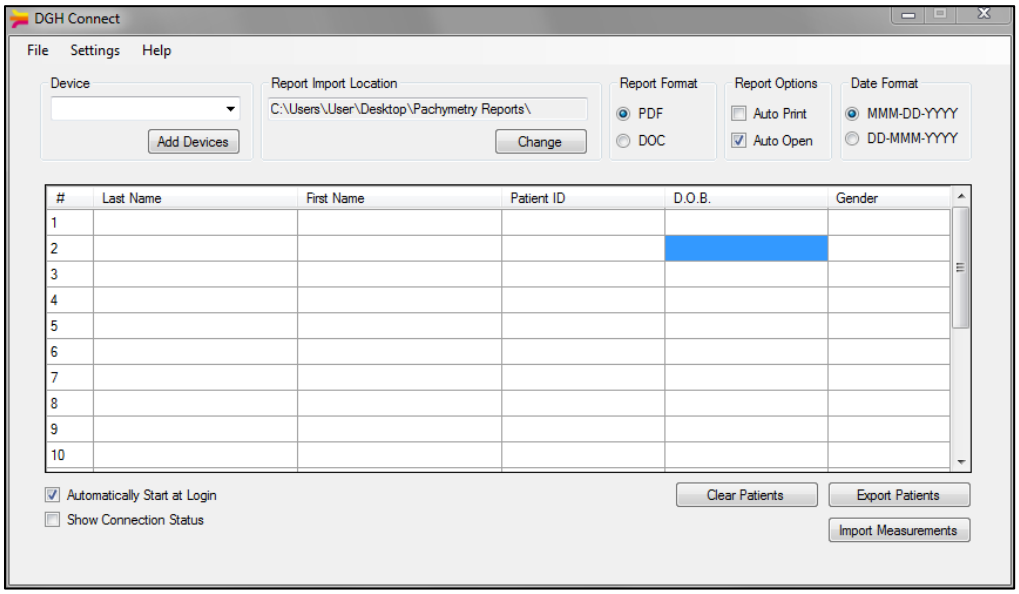
15.2.7 Click the 'Install' button and the software will complete installation.

15.2.8 Once installation is complete, click the icon created on the desktop to start the program.

15.3 Configuring the Software

Once the software has been installed, and the **Pachette 4** has been paired with the PC (See section 14.4) the DGH Connect software is ready to use. The operator determines how the patient records are imported. Below is a screenshot that shows the DGH Connect Software, with no patients added.

NOTE: The **Pachette 4** must be paired with the PC and COM Ports must be created before it can communicate with the DGH Connect Software (See section 14.4 and 14.5).

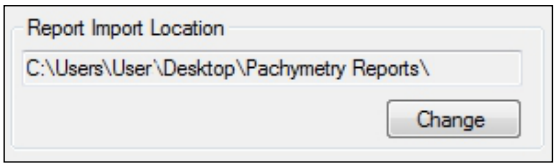


15.3.1 The **Device** selection box allows the user to select which DGH Bluetooth® enabled device to interact with. The Device box will list all devices that are associated with the DGH Connect Software by showing the model number and serial number.

- If no devices are shown in the list, it is necessary to add the device to the software's memory. See section 15.4 for information on adding the device.

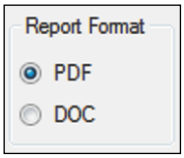
- To check the serial number of the **Pachette 4**, press and hold the CFG key.

15.3.2 The **Report Import Location** box allows the user to select where records will be stored when imported from the **Pachette 4**.



- Pressing the 'Change' button will open a dialog box that allows the user to select a custom import location.

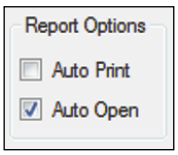
15.3.3 **Report Format** (default PDF) controls how the report will be imported from the device. Only one format can be selected at a time.



- If set to PDF, the report will be imported to the Report Import Location, as an un-editable PDF file.

- If set to DOC, the report will be imported to the Report Import Location, as an editable DOC file.

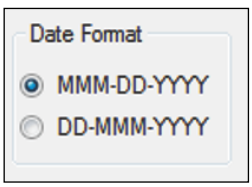
15.3.4 **Report Options** (default Auto Open enabled) control how the report will be processed once it has been saved to the PC. One, both or none of these options can be selected at the same time.



- If Auto Print is enabled, the report(s) will automatically be sent to the default system printer when imported.

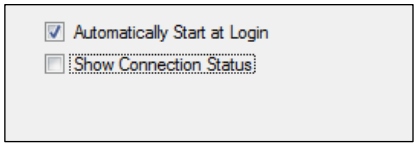
- If Auto Open is enabled, the report(s) will automatically be opened using the viewer for the appropriate file type.

15.3.5 **Date Format** (default MMM-DD-YYYY) determines how the date will be displayed.



- If the date format is changed in the DGH Connect Software, the **Pachette 4** will set to match it the next time records are sent from the PC to the **Pachette 4**.

15.3.6 Automatically Start At Login (default Enabled) determines if the software automatically starts when a user logs in to the computer.



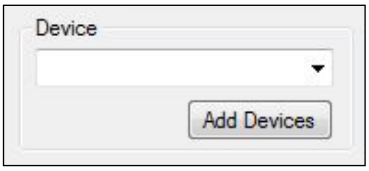
15.3.7 Show Connection Status (default Disabled) will open a box that shows connection status between the PC and **Pachette 4**.

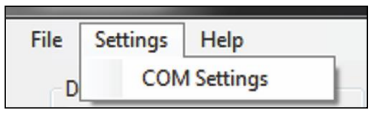
15.4 Adding a device

After the device has been paired with the PC, it can be selected for use from within the DGH Connect software.

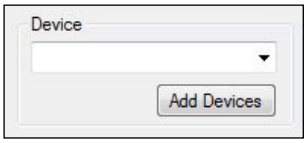
NOTE: The **Pachette 4** must be paired with the PC and COM Ports must be created before it can communicate with the DGH Connect Software (See section 14.4 and 14.5).

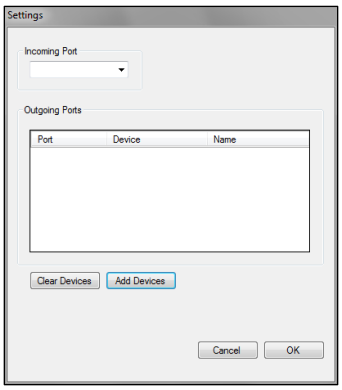
15.4.1 Adding a device can be done by clicking the 'Add Devices' button under the Device selection box, or by going to Settings → COM Settings at the top of the window.





15.4.2 Click the 'Add Devices' button from the main page or from the 'Settings' dialog box.

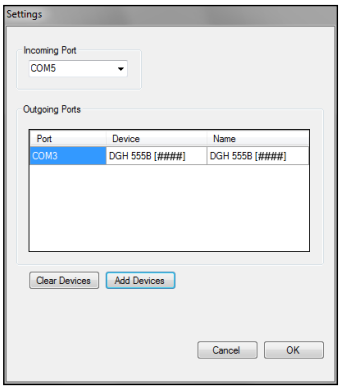




15.4.3 The software will prompt you to check that the device is powered on and paired. Confirm that the **Pachette 4** is on and click ‘OK’

Search for Devices
Please ensure that the devices you wish to add have been PAIRED with the PC and are POWERED ON before proceeding.
OK
Cancel

15.4.4 The software will automatically find paired devices and add them to the list of devices.



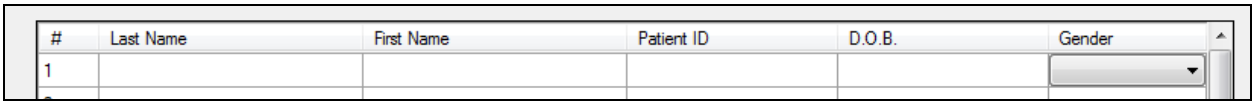
NOTE: From the ‘Settings’ dialog box, the user has the option to assign a unique name in the ‘Name’ field. This is to assist the user in distinguishing between units.

15.5 Exporting Patient Information to the Pachette 4

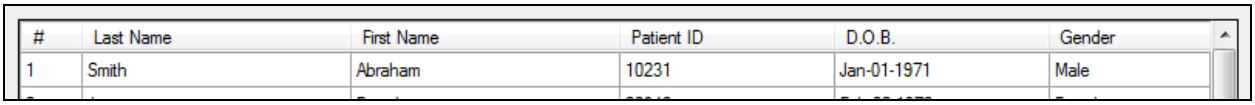
The DGH Connect Software is designed to allow the user to quickly input patient identification information into the **Pachette 4**. The following steps explain how to send patient identification information to the **Pachette 4**.

15.5.1 In the ‘Device’ selection box, choose which device is to receive the patient files.

15.5.2 Input the patient Last Name, First Name, Patient ID (number) D.O.B. and gender in the table. To do this, select the field you wish to edit and begin typing.



#	Last Name	First Name	Patient ID	D.O.B.	Gender
1					



#	Last Name	First Name	Patient ID	D.O.B.	Gender
1	Smith	Abraham	10231	Jan-01-1971	Male

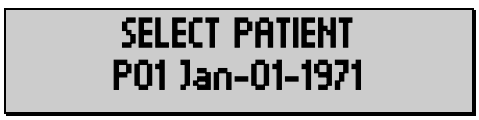
- There are 20 numbered rows for inputting patient information. When imported, the **Pachette 4** will store this information in a similarly numbered patient location.

15.5.3 When all of the patient information is entered, press the 'Export Patients' button located at the lower right-hand corner of the table.

15.5.4 The **Pachette 4** will briefly display a message 'Bluetooth Connected' and beep when it has started receiving files. It will display 'Bluetooth Disconnected' and beep when all files have been received.

15.5.5 After the files have been received, press the CFG key on the **Pachette 4**. The device will display the 'Select Patient' menu. Press the ▲ or ▼ key to scroll through the patient files.

- Pressing the OD or OS key while a patient's name is displayed will show additional identifying information for that patient.



15.6 Initiating measurement transfer using the PC software.

15.6.1 Check that the **Pachette 4** is placed in the correct Patient Mode:

- If in Single Patient Mode, only the single patient measurements will be retrieved by the computer.
- If in Multi Patient Mode, all measurements in the patient memory locations will be retrieved by the computer.

15.6.2 In the 'Device' selection box, choose which device the software is to receive measurements from.

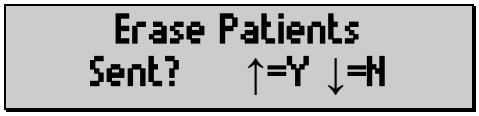
15.6.3 Press the 'Import Measurements' button located at the lower right-hand corner of the table.

NOTE: If there are no measurements stored in the device, the software will display the message 'No Measurements Exist for Selected Patient(s)'

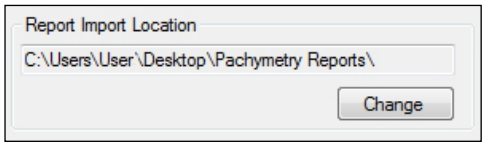
15.6.4 Once connected, the **Pachette 4** will display 'Bluetooth Connected' and will transfer measurements to the PC automatically.

15.6.5 Once all files are transferred, the device will automatically disconnect and show the 'Bluetooth Disconnected' message.

15.6.6 The **Pachette 4** will display the message 'Erase Patients Sent?' Selecting 'Yes' will clear all information of the patient(s) that was exported.

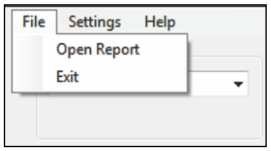


15.6.7 The software will automatically import patient records and save them to the directory indicated in the Report Import Location box.

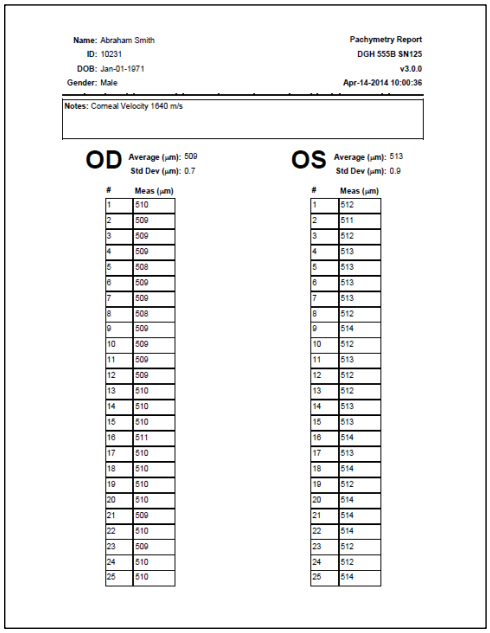


- If 'Auto Open' is enabled, the software will open each patient record in its own window.
- If 'Auto Print' is enabled, the software will print all patient records from the default system printer.

15.6.8 To open the patient reports that have been imported, go to the File → Open Report. The software will open a window that shows all patient records that have been imported.



15.6.9 The report will show all measurement and patient information. .PDF reports cannot be edited. .DOC reports can be edited using a word processing program.



Name: Abraham Smith
ID: 10231
DOB: Jan-01-1971
Gender: Male

Pachymetry Report
DGH 555B SN125
v3.0.0
Apr-14-2014 10:00:36

Notes: Corneal Velocity 1640 m/s

OD Average (µm): 509 Std Dev (µm): 0.7

#	Meas (µm)
1	510
2	509
3	509
4	509
5	508
6	509
7	509
8	508
9	509
10	509
11	509
12	509
13	510
14	510
15	510
16	511
17	510
18	510
19	510
20	510
21	509
22	510
23	509
24	510
25	510

OS Average (µm): 513 Std Dev (µm): 0.9

#	Meas (µm)
1	512
2	511
3	512
4	513
5	513
6	513
7	513
8	512
9	514
10	512
11	513
12	512
13	512
14	513
15	513
16	514
17	513
18	514
19	512
20	514
21	514
22	514
23	512
24	512
25	514

15.7 Initiating measurement transfer using the Pachette 4.

15.7.1 Check that the **Pachette 4** is placed in the correct Patient Mode:

- If in Single Patient Mode, only the single patient measurements will be retrieved by the computer.
- If in Multi Patient Mode, all measurements in the patient memory locations will be retrieved by the computer.

15.7.2 Check that the device is sending to a PC:

- If the device has already been pre-configured to send to a PC, press and hold the ENT key. The **Pachette 4** will attempt to send measurements. (Go to 15.7.5)
- If you are unsure if the device is pre-configured, check that the **Pachette 4** is sending the records to the proper device. To do this, press the CFG key to enter the Configuration Menu and repeatedly press the ENT key to navigate to the 'Send Meas To' menu.

15.7.3 Use the ▲ and ▼ keys to scroll through the saved configurations.

- NAME is the name of the device that will receive the records.
- $\#^{\mathbf{A}}$ is the list number of the device shown.
- $\#^{\mathbf{B}}$ is the total number of devices paired with the **Pachette 4**. Up to 5 devices can be paired at a time.
- Send → indicates that pressing the OD key will cause the **Pachette 4** to transmit measurements to the currently displayed device.

15.7.4 With the desired device displayed, press the OD key to select 'Send'.

15.7.5 The **Pachette 4** will begin connecting to the PC and display the message 'Connecting To BT Device'.

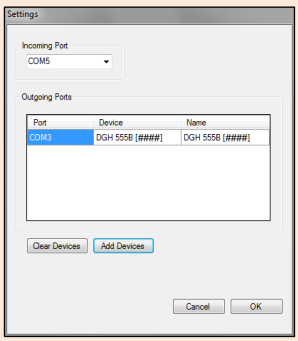
NOTE: If there are no measurements stored in the device, the **Pachette 4** will not attempt to connect. It will display the message 'No Measurements To Transfer!'

15.7.6 Once connected, the **Pachette 4** will display 'Bluetooth Connected' and will transfer measurements to the PC automatically.

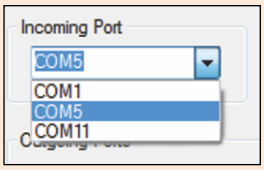
NOTE: If the incorrect incoming COM Port is selected, the **Pachette 4** will not be able to initiate measurement transfer. To correct this error:

15.7.6a Select Settings → COM Settings.

15.7.6b When the Settings dialog box opens, change the port by going to the Incoming Port selection box and choosing a different COM Port from the list. The computer will automatically save the new COM Port configuration.

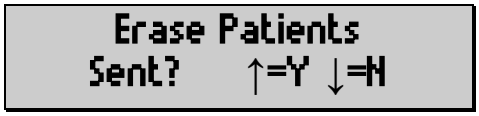


15.7.6c If this error occurs again, select another COM Port and attempt another import.

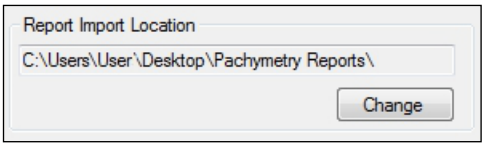


15.7.7 Once all files are transferred, the device will automatically disconnect and show the 'Bluetooth Disconnected' message.

15.7.8 The **Pachette 4** will display the message ‘Erase Patients Sent?’ Selecting ‘Yes’ will clear all information of the patient(s) that was exported.



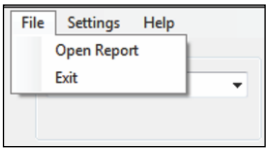
15.7.9 The patient reports will be stored in the ‘Report Import Location’ that is listed in the DGH Connect Software.



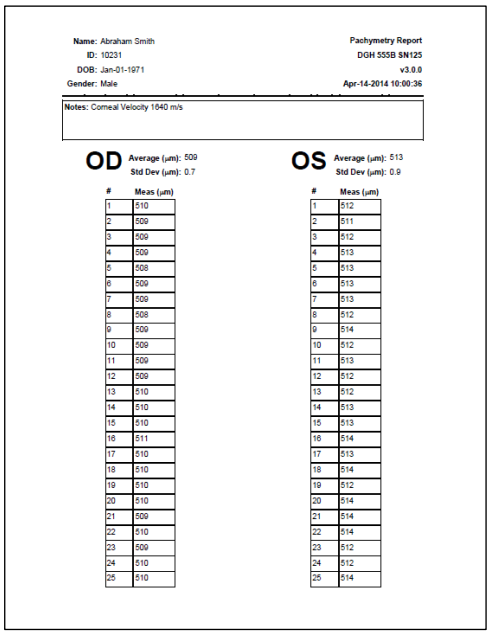
- If ‘Auto Open’ is enabled, the software will open each patient record in its own window.

- If ‘Auto Print’ is enabled, the software will print all patient records from the default system printer.

15.7.10 To open the patient reports that have been imported, go to the File → Open Report. The software will open a window that shows all patient records that have been imported.



15.7.11 The report will show all measurement and patient information. .PDF reports cannot be edited. .DOC reports can be edited using a word processing program.



Name: Abraham Smith
ID: 10231
DOB: Jan-01-1971
Gender: Male

Pachymetry Report
DGH 555B SN125
v3.0.0
Apr-14-2014 10:00:36

Notes: Corneal Velocity 1640 m/s

OD Average (µm): 509 Std Dev (µm): 0.7

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1	510
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OS Average (µm): 513 Std Dev (µm): 0.9

#	Meas (µm)
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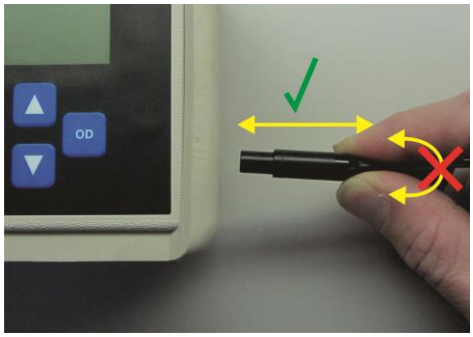
23	512
24	512
25	514

16. Changing Batteries

Please observe the following instructions when changing batteries to avoid damaging the device.

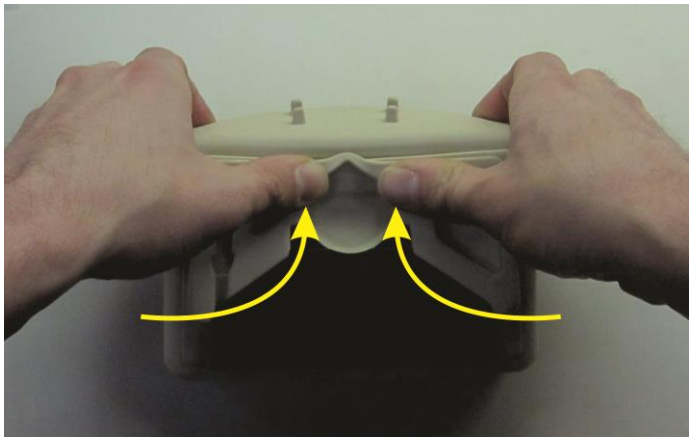
16.1 Removing the molded rubber case

16.1.1 Detach the probe entirely from the **Pachette 4** (See section 7.1). The probe pulls straight out from the connector. DO NOT TWIST THE PROBE CONNECTOR. Place the probe in a safe place, being careful to avoid any surface that could scratch or damage the probe tip.



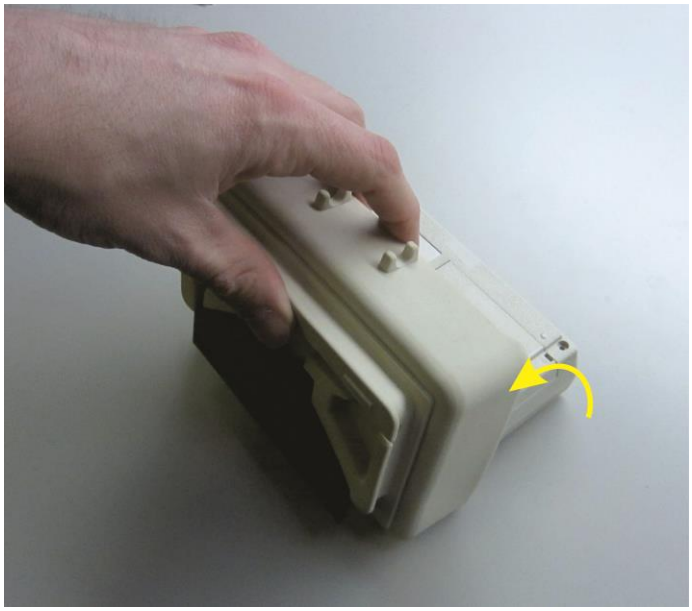
16.1.2 Place the **Pachette 4** face down on a clean, flat surface.

16.1.3 Place the left hand with 3 fingers under the top left corner of the rubber case, and the left thumb on the back of the rubber pad.



16.1.4 Place the right hand with 3 fingers under the top right corner of the rubber case, and the right thumb on the back of the rubber pad.

16.1.5 With the bottom edge of the unit still making contact with the flat surface, press with both thumbs until the unit is free of the holster.



16.1.6 Once the top edge is free, pull the holster off of the device.

16.2 Changing the Batteries

WARNING: Use only Alkaline or NiMH rechargeable batteries.

16.2.1 Slide open the battery door to gain access to the batteries.

16.2.2 Remove the discharged batteries and install new batteries following the orientation shown in the battery compartment.

16.2.3 Re-insert the device into the holster by placing the left side of the **Pachette 4** into the holster first, and then pressing the right side down into the holster.

16.2.4 Verify that the round opening is aligned with the probe connector of the **Pachette 4**.

16.2.5 Re-connect the probe by pushing it straight into the connector. DO NOT TWIST THE PROBE CONNECTOR.

16.2.6 Power up the unit by pressing the PWR key. You will be prompted to identify the type of batteries used. Select the appropriate type.

- You will receive a message indicating that the time and date must be reset. (See section 13.4.7)

17. Care and Maintenance

17.1 Cleaning and Disinfecting the Probe

Keep the probe tip clean and disinfected to prevent patient-to-patient infection. After each patient, wipe the probe with a Q-tip soaked in 70% isopropyl alcohol, and then immerse the probe tip (the clear cone) for 10 minutes in 70% isopropyl alcohol. The tip should be rinsed in sterile distilled water before using.

⚠ **WARNING:** The probe should NEVER be autoclaved or subjected to intense heat. As a general rule, the above cleaning instructions are sufficient to disinfect the probe in ordinary use. Do not scratch or chip the conical probe tip, which makes contact with the cornea.

The following disinfectants were found to be compatible with the probe tip material:

Disinfectant	Concentration Tested*
Cavicide Solution	(10-20%) Isopropyl Alcohol and (1-5%) Ethylene Glycol Monobutyl Ether
Cavicide Wipe	(10-20%) Isopropyl Alcohol and (1-5%) Ethylene Glycol Monobutyl Ether
Cidex	2.55% (w/w) Glutaraldehyde
Cidex OPA	6.2% by (w/w) Ortho-Phthalaldehyde (1,2 – benzenedicarboxaldehyde)
Isopropyl Alcohol	70% (v/v) Isopropyl Alcohol
Household Bleach	0.6% (w/w) Sodium Hypochlorite
Hydrogen Peroxide	3% (w/w) H_2O_2
Milton	2% (w/w) Sodium Hypochlorite

** The concentrations listed in this table are the specific concentrations that were tested by DGH to ensure compatibility with the probe tip material. DGH does not endorse or recommend the concentrations listed in the table above.*

⚠ **WARNING:** DGH makes no claims about the biological effectiveness as a disinfectant of any of the products listed above. Furthermore, DGH makes no claims regarding the effectiveness of any of these products for killing any known, or unknown, bacteria, virus, or other micro-organisms. DGH only claims that these products, when used properly, will not harm the transducer tip.

17.2 Cleaning The Unit

The unit's plastic housing and protective holster can be cleaned using a mild soap and water.

17.3 Transport and Storage Conditions

The **Pachette 4** is capable, while packed for transport or storage, of being exposed for a period not exceeding 15 weeks to environmental conditions not outside the following ranges:

- An ambient temperature range of -40°C to 70°C.
- A relative humidity range of 10% to 100%, including condensation.
- An atmospheric pressure range of 500 hPa to 1060 hPa.

17.4 Operating Conditions

The **Pachette 4** should be operated between temperatures of +18°C (64.4°F) to +40°C (104°F).

18. Troubleshooting Guide

PROBLEM / ERROR MESSAGE	POTENTIAL CAUSE	SOLUTION
Device will not turn on	Dead batteries	Replace batteries See section 16
Device screen is blank	In Sleep Mode	Press the PWR button See section 9.3
Screen is on, but will not take measurement.	In Standby Mode (indicated by blinking black cursor in upper left-hand corner)	Press the PWR button See section 9.2
'Plug In Probe' Message on screen	Probe is wet or has a residue on it	Dry probe See section **Error! Reference source not found.** and 7.4
'Check Probe' message on startup.	Probe is wet or has a residue on it	Dry probe See section **Error! Reference source not found.** and 7.3
Will not initiate CalBox mode	While device is off, hold down the DEL key and press the PWR key	Device starts in CalBox mode See section 8
Black boxes across the top half of the screen	1. Bad battery contact 2. Dead batteries	1. Clean battery contacts 2. Replace batteries See section 16
Slow measurement cycle	1. Dented/scratched probe tip 2. 'Auto Rep Delay' configuration	1. Replace probe. Contact DGH Technology. See section 19 2. Adjust configuration See section 13.2.3
Cannot send files to PC/printer	1. Bluetooth not enabled 2. Devices not paired 3. COM settings incorrect	1. Enable Bluetooth module See section 14.1 2. Pair devices See section 14.2 and 14.4 3. Adjust COM settings See section 15.5.3
'Remote Device Not Found' error message when attempting to send measurements to the software	Pairing not established	Pair devices then add device to the software's device list. See section 14.4 and 15.4
Cannot find correct device on the **Pachette 4** when trying to export/print measurements	Pairing not established	Clear all pairing and re-pair with preferred device. See section 14.9 regarding clearing See section 14.3 and 14.4 regarding pairing

19. Service

If you are having problems with this unit, please refer to the appropriate sections of this manual. Most service calls result from a misinterpretation of the operation of the instrument, as described in the manual.

19.1 Repairs and Customer Support

WARNING: Do not modify or attempt to repair this equipment without the authorization of the manufacturer.

WARNING: ELECTRICAL SHOCK HAZARD. Do not open the unit. Refer servicing to qualified service personnel.

If you feel there is a problem with the unit or a probe, please contact the Customer Service Department at:

DGH Technology, Inc.
110 Summit Drive, Suite B
Exton, PA 19341

Phone: (610) 594-9100
Fax: (610) 594-0390
Web: www.dghkoi.com

- When contacting DGH Technology, Inc. please make note of the model and serial number for the unit and probe (See section 19.2). Service personnel use this to track the status of service calls.

19.2 Viewing Model and Serial Number

The model number and serial number are located on the back of the unit's plastic housing and can be viewed by removing the protective holster. This information can also be viewed on the device display by pressing and holding the CFG key while the unit is on.

The probe serial number is engraved on the side of the probe.

19.3 Warranty

DGH Technology, Inc. "DGH" warrants each new DGH 555B and its accompanying accessories (hereinafter called "Equipment") to be free from defects in material and workmanship for three (3) years from the date of delivery to the original purchaser. This warranty is not applicable to any defect that is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than DGH. This warranty does not apply if the Equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by DGH. It is further understood that the cost of servicing replaceable and expandable items including parts and labor made in connection with the routine maintenance services as described in such Operator's Manual is not covered under this warranty and is the responsibility of the purchaser. This warranty is strictly limited to replacement or repair of the part that is found to be defective in material and workmanship. At the option of DGH, said part shall be replaced or repaired free of charge, F.O.B. our factory by DGH.

DGH reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in Equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, expressed or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, DGH does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss or damage of personal property, or loss of revenue. DGH has neither assumed nor authorized any other person (including any distributor authorized to sell its Equipment) to assume for it any other liability in the connection with the sale of Equipment.

20. Manufactured By DGH Technology, Inc.

DGH TECHNOLOGY, INC.

110 SUMMIT DRIVE
SUITE B
EXTON, PA 19341
USA (610) 594-9100

21. Authorized European Representative

EMERGO EUROPE

EC REP

Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31.70.345.8570

22. Regulatory Compliance

22.1 EMI/EMC Compliance

The Electro Magnetic Interference and Compatibility testing of the DGH 555B Ultrasonic Pachymeter (**Pachette 4**) was performed to determine compliance with emissions and immunity requirements set forth by the European Community under the requirements of the EMC Directive (89/336/EEC).

Test for radiated emissions was performed. Test was performed according to:

EN55011:1998	Radiated Emissions

The system complied with the radiated emissions requirements throughout the test.

Tests for radiated and conducted immunity were performed per EN60601-1-1-2: 2002 requirements. Tests were performed according to:

IEC 61000-4-2:1995	Electrostatic Discharge
IEC 61000-4-3:1995	RF Susceptibility

The system complied with the radiated and conducted immunity requirements through-out the test.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The DGH 555B Pachette 4 is intended for use in the electromagnetic environment specified below. The customer or the user of the DGH 555B Pachette 4 should assure that it is used in such an environment.

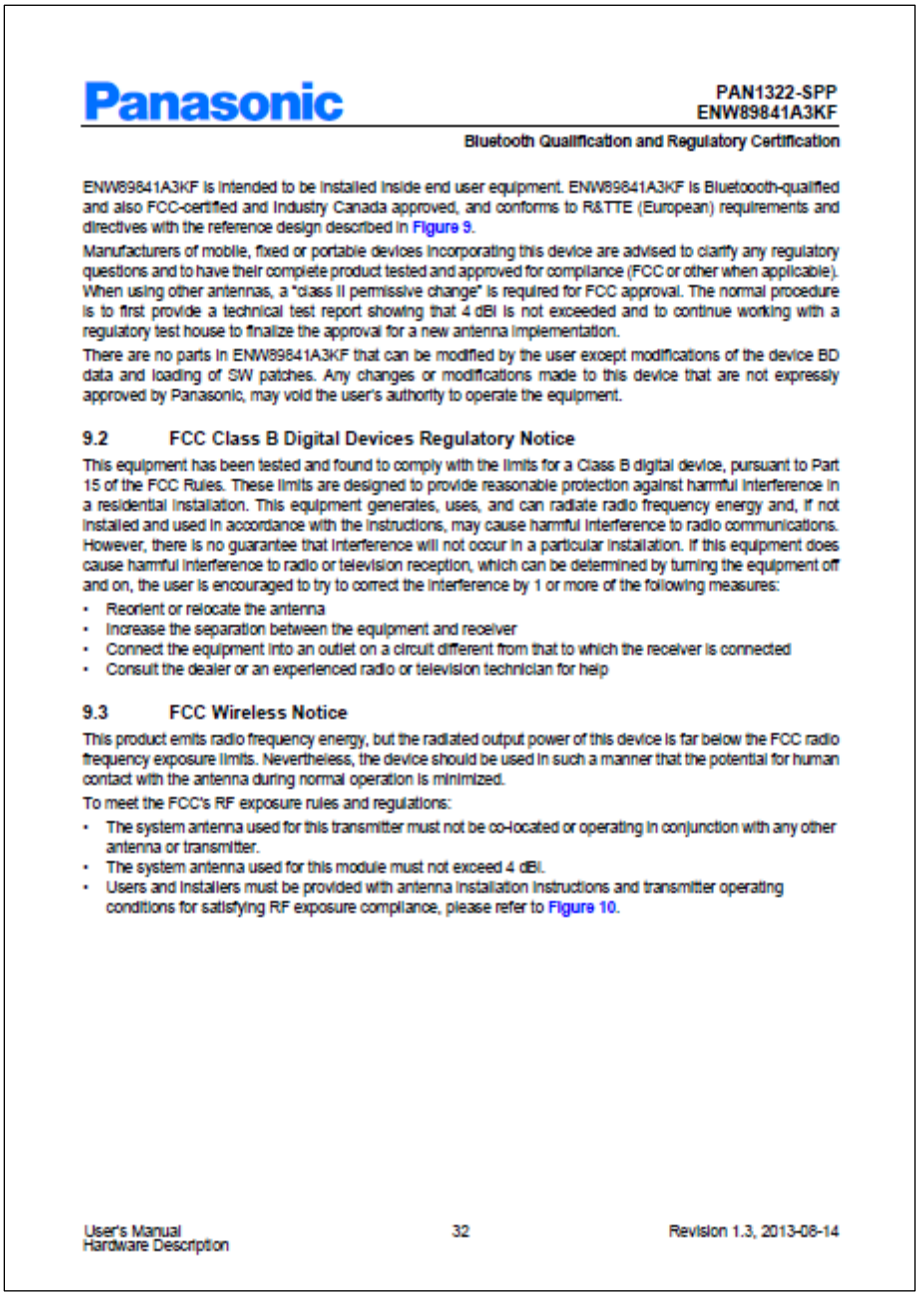
Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The DGH 555B Pachette 4 uses RF energy only for it's internal function. Therefore, it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The DGH 555B Pachette 4 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network power supply that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations / flicker emissions	NA	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The DGH 555B Pachette 4 is intended for use in the electromagnetic environment specified below. The customer or the user of the DGH 555B Pachette 4 should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies (E1=3V/m)	The DGH 555B Pachette 4 complies with requirements however a separation distance from mobile RF communications should be maintained based on the following calculations. $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz-800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz-2.5GHz where P is the transmitter power in watts and d is the recommended separation distance. The separation should include cables connected to the unit. Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	Complies (V1=3Vrms)	The DGH 555B Pachette 4 complies with requirements however a separation distance from mobile RF communications should be maintained based on the following calculations. $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ where P is the transmitter power in watts and d is the recommended separation distance. The separation should include cables connected to the unit.
Electrical fast transient IEC 61000-4-4	NA	NA	Not powered from mains
Surge IEC 61000-4-5	NA	NA	
Power frequency magnetic field IEC 61000-4-8	NA	NA	Unit does not use magnetically sensitive components.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	NA	NA	Not power from mains

22.2 Wireless Radio Module Regulatory Compliance



Panasonic

PAN1322-SPP
ENW89841A3KF

Bluetooth Qualification and Regulatory Certification

ENW89841A3KF is intended to be installed inside end user equipment. ENW89841A3KF is Bluetoooth-qualified and also FCC-certified and Industry Canada approved, and conforms to R&TTE (European) requirements and directives with the reference design described in Figure 9.

Manufacturers of mobile, fixed or portable devices incorporating this device are advised to clarify any regulatory questions and to have their complete product tested and approved for compliance (FCC or other when applicable). When using other antennas, a "class II permissive change" is required for FCC approval. The normal procedure is to first provide a technical test report showing that 4 dBi is not exceeded and to continue working with a regulatory test house to finalize the approval for a new antenna implementation.

There are no parts in ENW89841A3KF that can be modified by the user except modifications of the device BD data and loading of SW patches. Any changes or modifications made to this device that are not expressly approved by Panasonic, may void the user's authority to operate the equipment.

9.2 FCC Class B Digital Devices Regulatory Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by 1 or more of the following measures:

- Reorient or relocate the antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio or television technician for help

9.3 FCC Wireless Notice

This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.

To meet the FCC's RF exposure rules and regulations:

- The system antenna used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- The system antenna used for this module must not exceed 4 dBi.
- Users and installers must be provided with antenna installation instructions and transmitter operating conditions for satisfying RF exposure compliance, please refer to Figure 10.

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Image from Panasonic Corporation PAN1322-SPP User Manual Rev 1.3

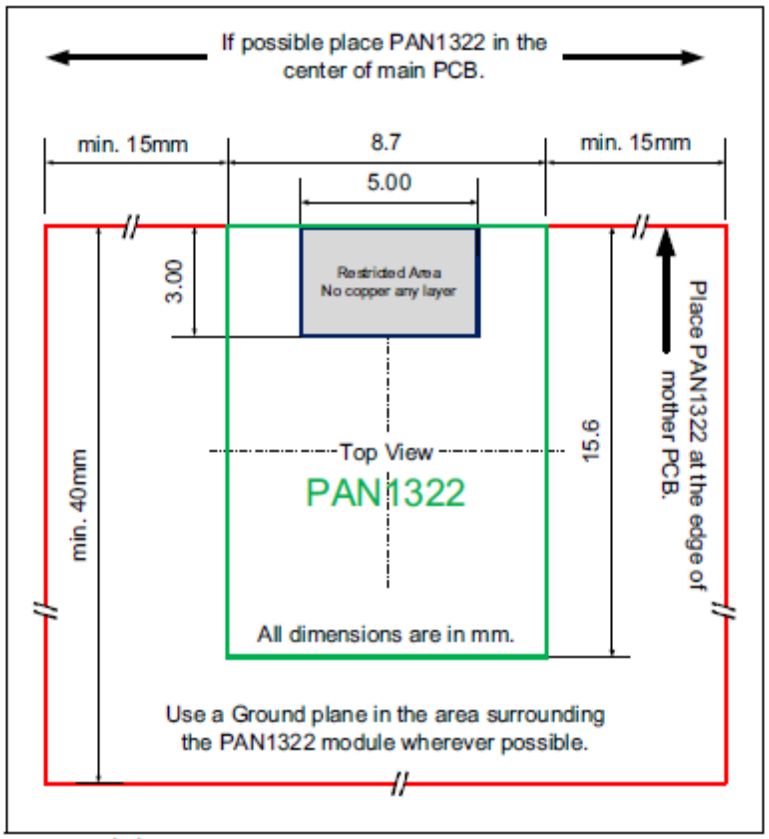

Figure 10 Cutout Drawing

Manufacturers of mobile, fixed or portable devices incorporating this module are advised to clarify any regulatory questions and to have their complete product tested and approved for FCC compliance.

9.4 FCC Interference Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference

Image from Panasonic Corporation PAN1322-SPP User Manual Rev 1.3

2. This device must accept any interference received, including interference that may cause undesired operation.

9.5 FCC Identifier

FCC ID: T7VEBMU

9.6 European R&TTE Declaration of Conformity

Hereby, Panasonic Industrial Devices Europe GmbH, declares that the Bluetooth module ENW89841A3KF is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

As a result of the conformity assessment procedure described in Annex III of the Directive 1999/5/EC, the end-customer equipment should be labelled as follows:

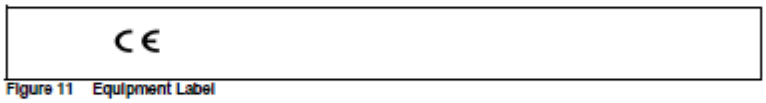

Figure 11 Equipment Label

PAN1322 in the specified reference design can be used in the following countries:

Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, The Netherlands, the United Kingdom, Switzerland, and Norway.

Image from Panasonic Corporation PAN1322-SPP User Manual Rev 1.3

Declaration of Conformity (DoC) 1999/5/EC

We, Panasonic Industrial Devices Europe GmbH
Wireless Connectivity, Power Electronics R&D Center
Zeppelinstrasse 19, 21337 Lueneburg, Germany

declare under our sole responsibility that the product:

Type of equipment: Bluetooth Module

Brand name: PAN1321 / PAN1311
PAN1322 / PAN1312

Model name: ENW89811K4CF / ENW89810K5CF
ENW89841A3KF / ENW89841C3KF

to which this declaration relates, is in compliance with all the applicable essential requirements, and other provisions of the European Council Directive:

1999/5/EC	Radio and Telecommunications Terminal Equipment Directive (R&TTE)

The conformity assessment procedure used for this declaration is Annex IV of this Directive.

Product compliance has been demonstrated on the basis of:

- EN 50371: 2002-11 - EN 60950-1: 2011-01	For article 3.1 (a) : Health and Safety of the User
- EN 301 489-1 V1.9.1 (2011-04) - EN 301 489-17 V2.1.1 (2009-05)	For article 3.1 (b) : Electromagnetic Compatibility
- EN 300 328 V1.7.1 (2006-10)	For article 3.2 : Effective use of spectrum allocated

The technical contruction file is kept available at:
Panasonic Industrial Devices Europe GmbH, Zeppelinstrasse 19, 21337 Lueneburg, Germany

Issued on: 31st of October 2012

Signed by the manufacturer:

(Company name) Panasonic Industrial Devices Europe GmbH

(Signature) Panasonic Industrial Devices Europe GmbH Zeppelinstraße 19 21337 Lueneburg Tel.: +49 (0) 4131 / 899-0

(Printed name) Heino Kaehler

(Title) Manager Wireless Connectivity

Figure 12 Declaration of Conformity

Image from Panasonic Corporation PAN1322-SPP User Manual Rev 1.3

9.7 Bluetooth Qualified Design ID

Panasonic has submitted End Product Listing (EPL) for PAN1322, based on Intel eBMU plattform, in the Qualified Product List of the Bluetooth SIG. These EPL are referring the Bluetooth qualification of the SPP-AT application running on the eBMU chip under QD ID B021246.

Manufacturers of Bluetooth devices incorporating PAN1322 can reference the same QD ID number.

Bluetooth QD ID: B021245 (PAN1322 SPP BT2.1).

9.8 Industry Canada Certification

PAN1322 complies with the regulatory requirements of Industry Canada (IC), license: IC: 216Q-EBMU

Manufacturers of mobile, fixed or portable devices incorporating this module are advised to clarify any regulatory questions and ensure compliance for SAR and/or RF exposure limits. Users can obtain Canadian information on RF exposure and compliance from www.ic.gc.ca.

This device has been designed to operate with the built in antenna. It is not allowed to alter the antenna or connecting an external antenna to the module. The built in antenna used for this transmitter must not be collocated or operating in conjunction with any other antenna or transmitter.

9.9 Label Design of the Host Product

It is recommended to include the following information on the host product label:

Contains transmitter Module FCC ID: T7VEBMU / IC: 216QEBMU

9.10 Regulatory Test House

The test house used by Panasonic in the Bluetooth and Regulatory approvals for the module PAN1322:

Eurofins Product Service GmbH
Storkower Str. 38c
D-15526 Reichenwalde b. Berlin
GERMANY
Tel.: +49 33631 888 0
Fax: +49 33631 888 650
www.eurofins.com

Image from Panasonic Corporation PAN1322-SPP User Manual Rev 1.3